UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Civil Action No. 05-11805-NMG
v.	:	
RICHARD F. SELDEN,	:	
Defendant.	:	
RICHARD F. SELDEN,	:	
Plaintiff,	:	Civil Action No. 06-11807-NMG
v.	:	
UNITED STATES FOOD AND DRUG ADMINISTRATION and ANDREW C. VON ESCHENBACH, in his official capacity as acting commissioner of the United States Food and Drug Administration,	:	
Defendants.	:	

NOTICE OF FILING

Pursuant to this Court's instructions at the conclusion of the November 3, 2006 hearing on Richard F. Selden's ("Dr. Selden's") Motion for Preliminary Injunction, see Civ. No. 06-11807-NMG (Docket No. 20), Dr. Selden yesterday filed with the United States District Court for the District of Columbia an Emergency Motion To Compel Food And Drug Administration Compliance With [The D.C. Court's] August 16, 2006 Order, Dr. Selden's Memorandum In Support, and associated attachments. The Securities and

Exchange Commission assented to Dr. Selden's request for the D.C. Court to treat the motion on an emergency basis; the Food and Drug Administration did not assent.

Attached hereto is a copy of the papers filed in connection with the motion, with an index provided below:

Exhibit 1	Richard F. Selden's Emergency Motion To Compel Food And Drug Administration Compliance With This Court's August 16, 2006 Order (with exhibit)
Exhibit 2	Richard F. Selden's Memorandum In Support Of His Emergency Motion To Compel Food And Drug Administration Compliance With This Court's August 16, 2006 Order (with attachments)

Dated: November 9, 2006
Boston, Massachusetts

Respectfully submitted,

/s/ Justin J. Daniels
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CERTIFICATE OF SERVICE

I, Justin J. Daniels, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-registered participants on November 9, 2006.

Dated: November 9, 2006

/s/ Justin J. Daniels
Justin J. Daniels

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:		
SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Miscellaneous Case No. 05-0476 (RMU)
v.	:	(Related Cases:
	:	Civ. No. 05-11805-NMG
RICHARD F. SELDEN,	:	Civ. No. 06-11807-NMG
	:	Pending in the United States District
Defendant,	:	Court for the District of Massachusetts)
and,	:	
FOOD AND DRUG ADMINISTRATION,	:	**EXPEDITED**
	:	**HEARING REQUESTED**
Interested Party.	:	

RICHARD F. SELDEN'S EMERGENCY MOTION TO COMPEL FOOD AND DRUG ADMINISTRATION COMPLIANCE WITH THIS COURT'S AUGUST 16, 2006 ORDER

Richard F. Selden ("Dr. Selden") respectfully moves this Court on an emergency basis for an Order requiring the United States Food And Drug Administration ("FDA") to comply with this Court's August 16, 2006 Order granting his motion to compel FDA compliance with two federal subpoenas issued on October 28, 2005.

At the November 3, 2006 pretrial conference in the related SEC enforcement action in the District of Massachusetts, the Court there recognized the need for resolution of compliance with the subpoenas in this case in order to permit the pretrial schedule there to proceed. On November 3, the District of Massachusetts Court extended by 90 days that pretrial schedule, directing that Dr. Selden again move this Court for relief, and stating that it would be willing to involve itself in the process if the FDA's objections

to jurisdiction in Boston could be resolved. This Court has the power to enforce its Order and, as the subpoena-issuing court, has the power to enforce the subpoenas.

Because the pretrial schedule in that related action has been extended solely to address these subpoenas, Dr. Selden asks that this Court promptly act on this motion.

As further grounds for this motion, Dr. Selden respectfully refers to his Memorandum In Support, submitted herewith.

WHEREFORE, Dr. Selden respectfully requests that this Court enter an Order requiring the FDA to comply with the Court's August 16, 2006 Order. A proposed form of Order is attached hereto as Exhibit A.

REQUEST FOR EXPEDITED HEARING

Pursuant to the Federal Rules of Civil Procedure and Local Civil Rules 7(f), 16.2(b) and 78.1, Dr. Selden respectfully requests an expedited hearing on this motion. The SEC assents to the request for expedition; the FDA does not.

LOCAL RULE 7(M) STATEMENT

Counsel for Dr. Selden has conferred with opposing counsel pursuant to Local Civil Rule 7(m) and the motion is opposed.

Dated: November 8, 2006
Washington, D.C.

Respectfully submitted,

/s/ Joseph L. Barloon

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CERTIFICATE OF SERVICE

I, Joseph L. Barloon, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants and that paper copies will be sent on November 8, 2006, to those indicated as non-registered participants, specifically:

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Frank Huntington
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Boston District Office
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Boston, Massachusetts 02110

Dated: November 8, 2006

/s/ Joseph L. Barloon
Joseph L. Barloon

EXHIBIT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:		
SECURITIES AND EXCHANGE COMMISSION,		
Plaintiff,	:	Miscellaneous Case No. 05-0476 (RMU)
v.	:	(Related Cases: Civ. No. 05-11805-NMG
RICHARD F. SELDEN,	:	Civ. No. 06-11807-NMG
Defendant,	:	Pending in the United States District Court for the District of Massachusetts)
and,	:	
FOOD AND DRUG ADMINISTRATION,	:	
Interested Party.	:	

[PROPOSED] ORDER

Upon consideration of Richard F. Selden's ("Dr. Selden's") Motion To Compel Food And Drug Administration ("FDA") Compliance With This Court's August 16, 2006 Order, and upon consideration of all papers and proceedings herein, it is this ___ day of November, 2006,

ORDERED that Dr. Selden's motion is GRANTED, and it is

FURTHER ORDERED that:

(1) The FDA shall, on or before January 29, 2007, produce to Dr. Selden in unredacted form all Complete Response Letters ("CRLs") issued by CBER between January 1, 1998 and December 31, 2002, inclusive, including but not limited to CRLs issued for products that were not approved by CBER or the FDA, and

(2) The FDA shall, on or before January 29, 2007, produce to Dr. Selden in unredacted form all documents agreed by the parties to be produced pursuant to Exhibit A to the Joint Status Report submitted to this Court on August 25, 2006 (a copy of which is attached hereto), and it is

FURTHER ORDERED that the productions described herein shall be made subject to the entry of an appropriate protective order.

SO ORDERED.

UNITED STATES DISTRICT JUDGE

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
1. All FDA documents relating to FDA's consideration of surrogate endpoints for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, including, but not limited to, all: A) internal FDA correspondence and documents relating to Dr. Selden, TKT, Replagal, the Fabrazyme Biologic License Application ("BLA"), or any Fabrazyme-related Investigational New Drug Application ("IND"); and B) materials from the Jan. 2003 FDA advisory committee meeting relating to Replagal or Fabrazyme. FDA will not produce: - documents submitted by TKT - Fabrazyme documents relating exclusively to chemistry, manufacturing, or controls ("CMC") - Fabrazyme documents generated after 4/23/03	A) FDA has an estimated 15,375 pages of potentially responsive documents, requiring 768 hours of review time. Anticipated production date uncertain.[2] B) FDA has an estimated 3,500 pages of potentially responsive documents, requiring 175 hours of review time. Anticipated production date uncertain.
2. All FDA documents relating to FDA's consideration of dual approval for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 4, 6, and 7.	See timing for Schedule A request 1.
3. Every complete response letter ("CRL") issued by the FDA's Center For Biologics Evaluation And Review ("CBER") from 1987 to the present.	**Open Issue, see Ex. B infra.**	If this request is narrowed to include every CRL issued by CBER in 2000 and 2001, subject to the criteria listed below in Exhibit B, FDA has identified 30 CRLs responsive to this request, totaling an estimated 393 pages and requiring 20 hours of review time. Anticipated production date of 10/3/06.
4. All documents relating to Replagal.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 6, and 7.	See timing for Schedule A request 1.
5. All documents relating to TKT but not to Replagal.	No production necessary.	N/A

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
6. All documents relating to Dr. Selden.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 4, and 7.	See timing for Schedule A request 1.
7. All documents relating to Fabrazyme through 4/24/03.	FDA will produce all: A) CRLs sent to Genzyme regarding Fabrazyme; B) Genzyme responses to Fabrazyme CRLs, except portions relating exclusively to CMC; C) correspondence between Genzyme and FDA, in addition to CRLs and CRL responses, relating to Fabrazyme; D) portions of the original Fabrazyme BLA or any Fabrazyme-related IND relating to clinical, safety, efficacy and/or clinical trials; E) internal FDA correspondence and documents relating to the Fabrazyme BLA or any Fabrazyme-related IND, except documents generated after 4/23/03; and F) materials from the Jan. 2003 FDA advisory committee meeting relating to Fabrazyme, except the meeting transcript and materials submitted by TKT.	A) FDA has already identified an estimated 25 pages of responsive documents, requiring 1.25 hours of review time. Anticipated production date of 9/29/06. B) FDA has an estimated 75 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 7,500 to 37,500 pages) of potentially responsive documents, requiring between 375 and 1,875 hours of review time. Anticipated production date uncertain. C) Anticipated production date of 12/31/06. D) FDA has an estimated 46 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 4,600 to 23,000 pages) of potentially responsive documents, requiring between 230 and 1,150 hours of review time. This estimate does not include any documents from any Fabrazyme-related INDs, which may contain even more potentially responsive documents. Anticipated production date uncertain. E) See timing for Schedule A request 1. F) See timing for Schedule A request 1.
8. All documents relating to the SEC lawsuit or any other actual/possible lawsuit involving TKT or Replagal.	FDA will produce all responsive documents, except: - documents submitted by TKT - documents unrelated to Replagal	FDA has an estimated 500 pages of potentially responsive documents. Anticipated production date of 12/31/06.

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
9. All guidelines for CBER review of BLAs, INDs, trials, protocols, etc.	FDA will produce any internal FDA manuals, guidelines or templates available for reference or use, as of January 1, 1996 or later, in connection with the review of a BLA or IND.	FDA has an estimated 41,000 pages of responsive documents, requiring 2050 hours of review time. Anticipated production date uncertain.
10. Record retention schedules under 21 C.F.R. § 20.23(c)	FDA will produce its Headquarters Record Control Schedule, last updated on 12/31/89, which FDA represents was the applicable record retention schedule for the period 1990 to present.	FDA has already collected 104 pages of responsive documents. Anticipated production date of 9/1/06.
11. All documents relating to the dissolution/potential dissolution of CBER.	No production necessary.	N/A
12. Any proposed or final documents relating to guiding public disclosure of BLA status.	FDA will produce any internal FDA proposals or draft guidelines relating to the public disclosure, by the applicant, of the status of the applicant's BLA.	FDA's preliminary search has not identified any documents responsive to this request.
13. All documents relating to joint FDA/SEC coordination.	FDA will produce all correspondence and communications, and all documents reflecting, memorializing or referring to any correspondence or communications, between FDA and the SEC relating to Dr. Selden, TKT, Replagal, or any joint FDA/SEC efforts to enhance inter-agency cooperation.	In addition to those documents identified as responsive to Schedule A Request 8, FDA has an estimated additional 1000 pages of potentially responsive documents. Anticipated production date of 12/31/06.

[1] Productions will be made by four different components within FDA on a rolling basis, and the anticipated production date is the final date by which the production of this category of documents will be completed by all FDA components. Estimates of the number of FDA staff hours necessary for production are based on an estimated 3 minutes per page for review and redaction of documents. FDA will provide a privilege log no later than 90 days after the completion of the production of each category of documents described above.

[2] See Exhibit B, Open Issue 1.

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EXHIBIT 2

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE SUBPOENAS IN:		
SECURITIES AND EXCHANGE COMMISSION,	:	
Plaintiff,	:	Miscellaneous Case No. 05-0476 (RMU)
v.	:	(Related Cases: Civ. No. 05-11805-NMG Civ. No. 06-11807-NMG Pending in the United States District Court for the District of Massachusetts)
RICHARD F. SELDEN,	:	
Defendant,	:	
and,	:	
FOOD AND DRUG ADMINISTRATION,	:	**EXPEDITED HEARING REQUESTED**
Interested Party.	:	

RICHARD F. SELDEN'S MEMORANDUM IN SUPPORT OF HIS EMERGENCY MOTION TO COMPEL FOOD AND DRUG ADMINISTRATION COMPLIANCE WITH THIS COURT'S AUGUST 16, 2006 ORDER

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Dated: November 8, 2006

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PRELIMINARY STATEMENT

More than a year ago Richard F. Selden ("Dr. Selden"), former CEO of biotech firm Transkaryotic Therapies, Inc. ("TKT"), issued subpoenas to the United States Food and Drug Administration ("FDA") seeking materials critical to his defense against the Securities and Exchange Commission's ("SEC's") charges of securities fraud in S.E.C. v. Selden, Civ. No. 05-11805-NMG (D. Mass., filed Sept. 1, 2005) (the "SEC Action").[1]

On August 16, 2006, this Court granted Dr. Selden's motion to compel compliance with the subpoenas and denied the FDA's motion to quash. See Docket Nos. 18 & 19 (reported at S.E.C. v. Selden, 445 F. Supp. 2d 11 (D.D.C. 2006)). In its Memorandum Opinion, the Court specifically noted that "Selden wants these documents to prepare a defense to the pending action in the United States District Court for the District of Massachusetts. Thus, the FDA must engage Selden's request, and formulate a response, with dispatch (rather than place Selden's subpoena request at the back of the FOIA queue)." Id. at 14 n.7. The Court also directed the parties to submit a "joint status report outlining the parties' anticipated timing." Id. The parties filed the Joint Status Report with this Court (and, as per the Court's instructions, with the Massachusetts Trial Court) on August 25, 2006. See Docket No. 20.

The Joint Status Report accomplished several objectives:

First, it provided a means for the parties to negotiate the final terms of the FDA's agreed production. Indeed, in all but one (albeit very important) respect, see infra Section I.B., the parties reached agreement on every document request contained in the subpoenas. See Docket No. 20, Joint Status Report, Ex. A (attached hereto at Tab B).

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1 A copy of the SEC's Complaint is attached hereto at Tab A.

Second, it crystallized the parties' remaining disputes concerning the FDA's compliance with the Court's August 16, 2006 Order. See id., Ex. B (attached hereto at Tab C).

Third, it made clear that notwithstanding this Court's admonition to the FDA that Dr. Selden needed the documents for his defense in the SEC Action, the FDA had no intention of accommodating the pretrial schedule in the SEC Action, and would only be willing to produce the documents within the next 22 months (i.e., by the middle of 2008). Because Dr. Selden's only interest in obtaining FDA discovery is for his defense against the SEC's fraud charges, the FDA's 22-month timetable amounts to a failure to implement the Court's August 16 Order.

On September 28, 2006, the Massachusetts Trial Court held a status conference concerning the pretrial schedule in the SEC Action. Regarding the FDA's 22-month delay, the Court made the following observations:

> THE COURT: I've read the papers and the background of this matter and am, I guess, equally concerned with the district judge in the District of Columbia that you're not getting sufficient cooperation from the Food and Drug Administration. I would ask your opinion as to whether an order of this court as opposed to an order from the district court in the District of Columbia would be beneficial . . .
>
> I would be inclined, if I have jurisdiction, to compel somebody, whether it's the Boston representative of the Food and Drug Administration or the director of the Food and Drug Administration in Washington, D.C., to appear in this court to explain to me why it should take 22 months to produce documents in a matter that is time-sensitive and in which the documents need to be had. We wouldn't put up with this from a private litigant. And I don't see -- at least last I heard, the government works for the people and not the other way around. I don't see why such an order shouldn't be, (a), entered and, (b), complied with . . .

> It seems to this Court that you have been energetic in trying to get that discovery. I don't think you can be faulted, having gone out the month after the last -- the scheduling conference and commenced an effort that has now gone on for -- what, 11 or 12 months?

9/28/06 Status Conf. Tr. at 3 & 5-6 (attached hereto at Tab D).

Consequently, on October 5, 2006, Dr. Selden, after conferring with the SEC, initiated a civil action in the District of Massachusetts against the FDA, seeking declaratory and injunctive relief pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 701-06, the Mandamus Act, 28 U.S.C. § 1361, the Freedom of Information Act, 5 U.S.C. § 552, and the Federal Declaratory Judgment Act, 28 U.S.C. § 2201, to require the FDA's meaningful compliance with this Court's August 16, 2006 Order. On October 13, 2006, the Trial Court issued an order requiring the FDA to appear on November 3, 2006 and show cause:

> . . . why a preliminary injunction pursuant to Fed. R. Civ. P. 65 should not be issued requiring the FDA to comply, on or before November 30, 2006, with the Order of the United States District Court for the District of Columbia in S.E.C. v. Selden, Case No. 1:05-mc-00476-RMU (D.D.C.) entered on August 16, 2006, granting in its entirety Dr. Selden's motion to compel the FDA's compliance with two federal subpoenas in 2005.

See Notice of Court Action In Related Case, Docket No. 22, Ex. A.

On November 3, 2006, pursuant to the Order To Show Cause, the parties appeared before the Trial Court on Dr. Selden's preliminary injunction motion. At the conclusion of the hearing, the Court gave the following instructions:

> THE COURT: What I'm going to do is this: I'm going to extend the time periods for discovery that are either expired or about to expire 90 days. I'm going to instruct the plaintiff in this case, the defendant in the related case, that is Mr. Selden and its counsel, to pursue with all due diligence whatever remedy it believes, he believes, it has in the District Court for

> the District of Columbia with regard to the compliance by the Food and Drug Administration with the outstanding subpoenas, including, if he sees fit, any motion to that court to involve this Court in the process. That is, if there is an availability of transfer of jurisdiction over this matter -- the FDA claims there is none, I'm not so sure, but that is up to the plaintiff to follow up. But, in any event, to pursue as diligently as possible with the understanding that it has now a requirement that is put off by 90 days to complete the discovery in the SEC litigation.
>
> If either the plaintiff or the Food and Drug Administration want to further advise this Court on whether or not this Court can do anything further with respect to the controversy involving the discoverable documents, then I will entertain such further legal advice. Otherwise, I will take the matter under advisement, both the FDA's motion to dismiss and Mr. Selden's motion for a preliminary injunction. I'm not going to act upon them now. I'm going to review all of these papers. But with respect to the SEC case, the matter is delayed 90 days, but no more. We will see what transpires.
>
> The District Court of the District of Columbia should be advised of the matter present in this Court and understand what the status of the discovery order is here.

11/3/06 Hearing Tr. at 30-32 (attached hereto at Tab E).

Accordingly, pursuant to the Trial Court's instructions, Dr. Selden now moves this Court for action on the FDA's non-compliance with this Court's August 16, 2006 Order.

ARGUMENT

I. THE FDA IS FAILING IN TWO CRITICAL RESPECTS TO COMPLY WITH THIS COURT'S AUGUST 16 ORDER

A. The FDA Claims It Cannot Complete Production Until Mid-2008

The Trial Court has now extended the pre-trial calendar in the SEC Action twice, by a total of nine months, to accommodate the FDA's delay. As it noted during the last hearing: "It seems to me -- and just as a practical matter -- that this is the tail wagging

the dog." 11/3/06 Hearing Tr. at 19. The current schedule now requires all written discovery to be completed by January 29, 2007. Nevertheless, the FDA now says that it will need 22 months -- or until the middle of 2008 -- to complete the production. Surely this could not be the kind of "dispatch" or "prompt" response that this Court had in mind when granting Dr. Selden's motion to compel (see 445 F. Supp. 2d at 14 n.7), given that it would render the subpoenas essentially meaningless and deny Dr. Selden a fair defense against the government's enforcement action.

1. A Protective Order Is The Appropriate Solution

The FDA has articulated essentially one reason why its production will take 22 months: it asserts that it must engage in the time-consuming process of redacting from the production all information constituting trade secrets or the agency's deliberative process. However, there is a straightforward solution that would significantly streamline the FDA's production and cut the production time down dramatically; namely, a protective order. The Trial Court has already endorsed this approach:

> THE COURT: . . . [W]hy not agree to some sort of protective order that limits the disclosure of any of this information to only those involved in this lawsuit? It's not, as I understand it, the intent of anybody to publicize any of this material to the general public. Its only relevance is to the SEC's claim against the plaintiff in this proceeding. So why can't the Food and Drug Administration agree to some sort of a protective order to avoid the necessity of having to make this search more onerous than it would otherwise be?

11/3/06 Hearing Tr. at 8. It is correct that Dr. Selden has absolutely no interest in disclosing the materials beyond the SEC Action and is perfectly willing to agree to an order governing their disclosure.

During the November 3, 2006 hearing, the FDA's counsel asserted that the agency has no legal right to produce unredacted documents, even if ordered to do so by an Article III court. See, e.g., 11/3/06 Hearing Tr. at 9. However, as the FDA's own regulations demonstrate, that is simply not the case. The FDA's regulations specifically provide for the disclosure of otherwise non-public information in connection with court proceedings:

> Data and information otherwise exempt from public disclosure may be revealed in [FDA] administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The [FDA] will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

21 C.F.R. § 20.86 ("Disclosure in administrative or court proceedings") (emphasis added).[2]

Further, this is not the typical case of a private party fighting over commercial issues or seeking to challenge a drug approval or denial. Here, the federal government has charged an individual citizen with securities fraud, which is "akin to a criminal prosecution." S.E.C. v. Heartland Advisors, Inc., Civ. No. 03-1427, 2006 WL 2547090, *5 n.4 (E.D. Wis. Aug. 31, 2006). The government's conduct also implicates Dr. Selden's rights to due process. See S.E.C. v. Rivlin, Civ. No. 99-1455, 1999 WL 1455758, *3 (D.D.C. Dec. 20, 1999) (a defendant has "full due process rights" when "the SEC, pursuant to its investigation, either files a complaint or makes a criminal reference")

---

[2] The relevant statutory provisions governing confidentiality likewise contemplate such exceptions. See 28 U.S.C. § 1905 (prohibiting disclosure only to extent "not authorized by law"); 21 U.S.C. § 331(j) (permitting disclosure "to the courts when relevant in any judicial proceeding under this chapter").

(citation omitted).[3]

A protective order is precisely what is needed to protect the interests of the parties and should be entered here to permit prompt production of the subpoenaed materials pursuant to it.

2. In Any Event, The FDA Should Be Required To Produce All Documents By The January 29, 2007 Document Production Cut-Off In The SEC Action

Even if the Court declines to enter a protective order such that the FDA would be required to redact all documents to the extent necessary, the FDA's proposed 22-month schedule is not defensible. In response to the FDA's 22-month assertion, Dr. Selden now has agreed to limit his request for backup scientific reports so that none of those attachments need to be produced. Yet, the FDA's estimate of 22 months assumed both the delay needed for redaction and the need to review and produce scientific attachments. Neither is needed because a protective order obviates the former, and Dr. Selden has agreed not to require the latter. In addition, under the FDA's estimate, one person would need six weeks to review and process a single box of documents.[4] Even a conservative estimate of the review time in a complex litigation would be no more than four to five days per box -- and now much, much less time would be required than the

---

[3] Courts have expressly recognized the possibility of disclosure under such circumstances. See, e.g., U.S. v. W.R. Grace, --- F. Supp. 2d ---, Cr. No. 05-07-M, 2006 WL 2942707, *5 (D. Mont. Aug. 9, 2006) (court's protective order is an "authorization by law" for purposes of 28 U.S.C. § 1905); U.S. v. Niemoeller, Cr. No. IP02-0009-01-H/F, 2004 WL 1179446, *3 (S.D. Ind. May 17, 2004) (disclosure pursuant to 21 U.S.C. § 331(j) allowed "when the information is relevant to a judicial proceeding").

[4] This figure is derived as follows: The FDA estimates a total production of approximately 120,000 pages of documents. One standard size file box (or "banker's box") can hold approximately 2,500-3,000 pages of documents. FDA says it will take three people 22 months to complete this production, meaning that one person will need 22 months to complete approximately 13-16 boxes, or 6-7 weeks per box, per person. This estimate assumes Dr. Selden seeks the scientific attachments which often comprise the bulk of the documentation. He does not (see supra). Consequently, the pages sought are much less. Dr. Selden and TKT have themselves long ago produced more than 45,000 pages to the SEC, and the SEC received documents from the FDA.

FDA assumed if production occurs under a protective order without redaction or without production of scientific attachments. It is simply not reasonable for the FDA to insist on its drawn out schedule. The Court should order the FDA to comply with the subpoenas on a rolling, accelerated basis by no later than the end of the written discovery period in the SEC Action: January 29, 2007.

B. The FDA Should Be Ordered To Comply With Dr. Selden's Request No. 3 As Modified To 1998-2002

Importantly, Request No. 3, served October 2005, calls for the production of FDA Complete Response Letters (sometimes referred to as "Complete Review Letters" or "CRLs"). CRLs are official letters issued by the FDA to companies seeking domestic marketing approval for their products "when the complete review indicates that there are deficiencies remaining that preclude the approval of the application or supplement at that time." FDA Center for Biologics Evaluation and Research ("CBER") SOPP 8405, version #4 (eff. Sept. 20, 2004). Under FDA protocol, the CRL will: "Summarize all of the deficiencies remaining, and [w]here appropriate, describe actions necessary to place the application/supplement in a condition for approval." Id. Dr. Selden's original request sought the production of all CRLs issued by the FDA from 1987 to the present.

In response to the FDA's objection that such a request is burdensome, Dr. Selden has offered to narrow the request to only those CRLs issued between January 1, 1998 and December 31, 2002, inclusive, by CBER, including approved and non-approved products. See 11/3/06 Hearing Tr. at 30. However, the FDA agrees only to produce CRLs from 2000 and 2001 for approved products -- not for products (like Dr. Selden's) that were not approved by the FDA. That is an incomplete set of documents.

Any claim by the FDA that CBER's CRLs from January 1, 1998 to December 31, 2002 would be burdensome to produce is unpersuasive. CRLs are one of the FDA's central documents. CRLs are required by Congress to be submitted by the FDA to applicants in connection with the agency's statutory review deadlines set by the Prescription Drug User Fee Act ("PDUFA").[5] In addition, the dates of the CRLs are readily determinable because, by regulation, CBER is required to provide CRLs within 180 days of the initial submission of the application for approval.[6] This is not a request for miscellaneous administrative documents.

Further, the CRLs are critical to Dr. Selden's defense. TKT received such a CRL from the FDA in January 2001, as did TKT's "rival" Genzyme Corporation, in the FDA approval "race" about which the SEC has sued Dr. Selden. See, e.g., SEC Complaint (Tab A) ¶ 24. In total, five CRLs were sent to TKT and Genzyme, TKT's direct competitor in the race for approval, as part of the FDA application and review period taking place between 1998 and 2002. The SEC's complaint specifically focuses on this. See id. ¶ 13. Dr. Selden has subpoenaed the 1998-2002 CRLs to show that TKT's and Dr. Selden's response to CBER's CRL was normal, appropriate, and not improper as the SEC would have a jury believe, involving correct conduct, not deception. Those CBER CRLs from the same time frame as the CRLs for the TKT/Genzyme "race" focused upon by the SEC will permit Dr. Selden to prove his conduct was normal, proper and not deceptive. Further, TKT's application to the FDA was not approved by CBER. Consequently, the

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5 See, e.g., 21 U.S.C. § 379(g) (FDA's "process for the review of human drug applications" defined to include "[t]he issuance of action letters").

6 21 C.F.R. § 312.84(d) ("[Biologic] applications will be subject to the requirements and procedures contained in Part 314 or Part 600 of this chapter, as well as those in this subpart."); 21 C.F.R. § 314.100 (requiring action letter within 180 days).

FDA's resistance to providing CRLs for non-approved products (such as TKT's) deprives Dr. Selden of many of the very CRLs that he will use to show his responses were proper and not deceptive.

To the extent that this Court needs guidance from the Massachusetts Trial Court to resolve any of these issues, that Court has expressed its willingness to be helpful. As noted by the Trial Court during the November 3, 2006 hearing:

> THE COURT: The case at issue is pending in this court. The subpoena that we are fighting about bears upon the issues that are relevant to an action before this Court, not the District Court of the District of Columbia. And to say that this Court has no standing or jurisdiction to do anything to protect the integrity of its docket and to move its cases along doesn't strike me as logical.

11/3/06 Hearing Tr. at 19.

II. DR. SELDEN REQUESTS THE COURT'S EXPEDITED, EMERGENCY CONSIDERATION OF THIS MOTION

The Massachusetts Trial Court has now set a final cut-off of January 29, 2007 for the close of all document productions. That is 90 days extended from the already-extended pretrial schedule caused by the FDA delays. The FDA is a most critical witness for Dr. Selden's defense and without the requested discovery he will be substantially prejudiced in his ability to defend himself against the SEC's charges. Dr. Selden therefore respectfully requests that this Court consider his motion on an expedited, emergency basis. The SEC assents to this request; the FDA does not.

CONCLUSION

For all of the foregoing reasons, Dr. Selden respectfully submits that this Court should grant his motion and order the FDA to comply with the Court's August 16, 2006 Order.

Dated: November 8, 2006
Washington, D.C.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Joseph L. Barloon, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants and that paper copies will be sent on November 8, 2006, to those indicated as non-registered participants, specifically:

Jennifer L. Zachary
Trial Attorney
United States Department of
Health and Human Services
Office of the General Counsel
5600 Fishers Lane
Rockville, Maryland 20857

Frank Huntington
United States Securities and Exchange Commission
Boston District Office
33 Arch Street, 23rd Floor
Boston, Massachusetts 02110

Dated: November 8, 2006

/s/ Joseph L. Barloon
Joseph L. Barloon

TAB A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

v.

RICHARD B. SELDEN,

Defendant.

Civil Action No. 05 11805 NMG

COMPLAINT

Plaintiff Securities and Exchange Commission ("Commission") alleges the following against defendant Richard B. Selden ("Selden"):

SUMMARY

1. This case arises from material misrepresentations by Transkaryotic Therapies, Inc. ("TKT"), a bio-pharmaceutical company based in Cambridge, Massachusetts, and by defendant Selden, TKT's former CEO. Between at least October 2000 and October 2002, TKT and Selden misrepresented that clinical trials for TKT's flagship drug, Replagal, were a success and made positive statements about Replagal's chances of being approved for sale in the U.S. by the U.S. Food and Drug Administration ("FDA"). In fact, beginning in January 2001, the FDA had informed TKT that its principal clinical trial was a failure and that Replagal would not receive FDA approval based on that trial. At all relevant times, defendant Selden was the CEO of TKT and knew the negative information about Replagal. Nevertheless, he made, signed, participated in, or otherwise authorized a series of materially misleading public statements by TKT about the

status of the FDA application for Replagal. In addition, he sold 90,000 shares of TKT stock while in possession of material non-public information about the negative clinical results and other problems with the FDA application, thereby avoiding losses of more than $1.6 million that he would have incurred had he held the stock until October 2002 when TKT finally disclosed some of the negative information about the application and its stock price dramatically declined.

2. In June 2000, TKT filed an application for FDA approval of Replagal, a treatment for Fabry disease, a rare kidney condition in which patients suffer from extreme pain and kidney dysfunction. From at least October 2000 until it issued corrective disclosure in October 2002, TKT and Selden as CEO made a series of public statements and filed several reports to the Commission describing TKT's most important clinical trial (known as the "pivotal trial") as a success and containing positive statements about Replagal's clinical benefits and chances for FDA approval. However, TKT and Selden as CEO knew but failed to disclose material negative information about Replagal's FDA application such as: (1) the pivotal trial had failed to meet its primary objective; (2) the FDA had informed TKT in January 2001 that the pivotal trial was a failed study and that its primary analysis had failed; (3) the FDA had recommended in January 2001 that TKT conduct additional clinical trials; and (4) TKT had informed the FDA, at least as early as April 2001, that it would no longer seek approval of Replagal based on a claim that the drug was effective against pain.

3. After the market closed on October 2, 2002, TKT publicly announced that the FDA viewed the company's pain-related clinical data as "uninterpretable" and that, as a result, TKT had abandoned its claim that Replagal was clinically effective against pain as a basis for seeking FDA approval. During a conference call with investors that evening, Selden falsely

stated that TKT had only recently learned of the FDA's position and had just decided to change its approach to the application, when in fact the FDA had been communicating negative information to TKT since at least January 2001 and TKT had told the FDA in April 2001 that it was changing its approach. On October 3, 2002, the price of TKT stock plummeted 63% – from a closing price of $33.25 per share on October 2 to $12.75 per share on October 3.

4. Between May 2001 and February 2002, Selden sold 90,000 shares of TKT stock while he knew the material, non-public information about the problems with TKT's clinical trial and its FDA application for Replagal. Based on the closing price of TKT stock after the information was publicly disclosed on October 2, 2002, Selden avoided a loss of $1,664,000 and was unjustly enriched by selling his TKT stock during a period when the stock price was artificially inflated as a result of misleading information in the markets.

5. Through the activities alleged in this Complaint, Selden violated the anti-fraud provisions of the federal securities laws, specifically Section 17(a) of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §77q(a)] and Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5]. Selden also aided and abetted TKT's violations of Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20,13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 & 240.13a-13] by causing TKT to file false and misleading annual, quarterly and other reports with the Commission.

6. Accordingly, the Commission seeks: (a) entry of a permanent injunction prohibiting Selden from further violations of the relevant provisions of the federal securities laws; (b) disgorgement of Selden's ill-gotten gains, plus pre-judgment interest; (c) the imposition

of a civil penalty due to the egregious nature of Selden's violations; and (d) entry of an order barring Selden from serving as an officer or director of a public company.

JURISDICTION AND VENUE

7. This Court has jurisdiction over this action pursuant to Section 22 of the Securities Act [15 U.S.C. §77v] and Sections 21 and 27 of the Exchange Act [15 U.S.C. §§78u & 78aa]. Venue is proper in this District because, at all relevant times, TKT's corporate headquarters was in this District, many of the acts and practices alleged in this Complaint occurred in this District, and Selden lives in this District.

8. The Commission seeks a permanent injunction pursuant to Section 22 of the Securities Act [15 U.S.C. §77v] and Section 21(d)(1) of the Exchange Act [15 U.S.C. §78u(d)(1)]. The Commission seeks the imposition of a civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. §77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)]. The Commission seeks an officer and director bar pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)].

9. In connection with the conduct described in this Complaint, Selden directly and indirectly made use of the mails or the means or instruments of transportation or communication in interstate commerce.

DEFENDANT AND RELEVANT ENTITY

10. **Selden**, age 46, lives in Wellesley, Massachusetts. He founded TKT and served as its CEO and a director from 1988 until his resignation in February 2003.

11. TKT, a Delaware corporation, is a bio-pharmaceutical company headquartered in Cambridge, Massachusetts. From 1996 through July 2005, TKT common stock was registered with the Commission pursuant to Section 12(g) of the Exchange Act [15 U.S.C. §78l(g)] and traded on the NASDAQ National Market System. Pursuant to Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 13a-1 and 13a-13 thereunder [17 C.F.R. §§240.13a-1 and 240.13a-13], TKT was required to file with the Commission annual reports on Form 10-K and quarterly reports on Form 10-Q. Pursuant to Rule 12b-20 [17 C.F.R. §240.12b-20], TKT's annual and quarterly reports were required to contain such material information as necessary to make the required statements, in the light of the circumstances under which they were made, not misleading. On or about July 28, 2005, TKT was acquired by Shire Pharmaceuticals Group, PLC ("Shire") and became a wholly-owned subsidiary of Shire. As a result, TKT is no longer a publicly-traded company and no longer files periodic reports with the Commission.

STATEMENT OF FACTS

Replagal and its Significance for TKT

12. Replagal is intended to treat Fabry disease, a genetic disorder caused by the lack of a key enzyme. Fabry disease causes extreme pain, particularly in the hands and feet, cloudiness in the cornea of the eye, and hearing loss, and it may involve potentially life-threatening complications such as progressive kidney disease, heart attack, and stroke. The disease is extremely rare, with a U.S. patient population estimated at a few thousand, but treatment for the disease costs approximately $160,000 per patient annually. Replagal has been approved for use in some other countries and, at all relevant times, sales of Replagal abroad were TKT's only source of product revenue. Accordingly, the possibility that the FDA would approve

Replagal for sale within the U.S. was highly material to TKT.

13. In June 2000, TKT submitted an application for FDA approval for domestic sales of Replagal. TKT's application was based upon clinical trials whose principal objective, TKT hoped, was to demonstrate that Replagal had a treatment effect on the extreme pain suffered by patients with Fabry disease. About one week later, Genzyme Corp. ("Genzyme") filed a competing application for its drug, Fabrazyme. Genzyme's application was based upon surrogate marker data, an approach which is generally seen as a less desirable basis for obtaining FDA approval. Both applicants sought "orphan drug" status which, if granted, would result in a seven-year marketing exclusivity within the U.S. The existence of competing orphan drug applications was unprecedented and, because of the "winner-take-all" effect on the first applicant to receive FDA approval, any information about the FDA's attitude toward approval of Replagal would be watched closely by investors. As one analyst described the situation, "It's an amazingly high stakes poker game [TKT] is playing with [Genzyme] – if either company has a glitch in front of the FDA panel, that company may have to wait seven years for another chance."

Replagal's Clinical Trials

14. TKT's pivotal study, called TKT 003, was conducted at the National Institutes of Health. As indicated above, the primary objective or endpoint of the study was to demonstrate that Replagal had a treatment effect on pain. Prior to the study, TKT and the FDA agreed that the primary efficacy analysis (that is, the primary analysis upon which TKT would rely to demonstrate Replagal's clinical benefit for pain) would be an analysis referred to as "area under the curve" or "AUC".

15. The level of confidence in a statistical result is expressed in terms of probability, often known as a "*p* value". Under statistical principles, the smaller the *p* value, the greater the level of certainty that the observed effect was not randomly induced, and a *p* value of 0.05 or less (indicating a 95% level of certainty that the observed effect was not randomly induced) is generally accepted as persuasive. A *p* value higher than 0.05 is not *per se* evidence of failure, but further analysis is needed to assess whether the drug at issue caused the observed effect.

16. In TKT's pivotal study, the *p* value of the AUC analysis for effect on pain was 0.19 – much worse than the desired level of 0.05 or less. Based on this result, the pivotal study failed to meet its primary objective. Subsequent analysis enabled TKT to reduce the asserted *p* value to 0.08, which was still worse than the desired level of 0.05 or less. Although the AUC analysis did not produce a result with a *p* value of 0.05 or lower, two secondary pain analyses yielded *p* values of 0.02 and 0.05, respectively.

May 2000 Meeting with Institutional Investor

17. In May 2000, Selden and other senior TKT executives met privately with an institutional investor who was considering a substantial investment in TKT. At that meeting, Selden and other TKT executives presented the complete results of the pivotal study, including the fact that the one of the *p* values of the AUC analysis was 0.08. Based on the information provided, the investor had sufficient information to conclude in an investment memorandum that the pivotal study had failed to meet its primary objective. Selden also acknowledged to this investor the significant risk that, in light of these results, the FDA would not approve Replagal. After disclosing this negative information to the institutional investor – who was bound by a confidentiality agreement to keep the bad news secret – Selden and TKT embarked upon a

campaign to mislead the investing public about Replagal's chances for FDA approval.

TKT's Misleading Statements at Conference in October 2000

18. In October 2000, TKT representatives made a presentation concerning the pivotal study to medical professionals and investors at a conference sponsored by the American Society of Human Genetics ("ASHG"). TKT's presentation included a slide show, and Selden had reviewed and approved each slide in advance.

19. TKT's presentation described the successful results of the pivotal study with reference to the secondary pain analyses but never mentioned that the primary efficacy analysis (the AUC analysis) had failed to show a benefit (because its *p* value was 0.19). To the contrary, one of the slides purported to show the results of the primary efficacy analysis with a *p* value of 0.02, much better than the desired level of 0.05 or less for demonstrating statistical significance. Although the pivotal study did produce a secondary pain analysis with a *p* value of 0.02, the presentation omitted to say that the *p* value of the primary efficacy analysis was 0.19, much worse than 0.02. Selden had personally decided that TKT's presentation should not include any account of the AUC analysis.

20. TKT's characterization of the pivotal study at the ASHG conference was materially misleading and created the false impression in the investment community that the pivotal study was an unqualified success. For example, one analyst wrote after the conference that "positive pivotal trial results for Replagal were presented at the [ASHG] in October 2000.... Results showed Replagal to be effective in achieving all primary and secondary endpoints, as well as being safe and well-tolerated."

The FDA's Negative January 2, 2001 Review Letter

21. FDA rules require the agency staff to provide a response, known as a "complete review letter", within six months after the filing of an application for approval of a drug. On January 2, 2001, TKT received a complete review letter from the FDA which explicitly stated that TKT had failed to demonstrate the clinical benefits necessary for FDA approval:

> The clinical study data you have provided do not provide substantial evidence of efficacy for [Replagal].... [A]dditional analyses or otherwise revised analyses of the clinical data you have submitted will be unable to address this deficiency. In order to provide substantial evidence of efficacy, we recommend that you conduct additional clinical studies and submit the results to [FDA].

The review letter explained that TKT had failed to demonstrate the efficacy of Replagal or even a statistically significant difference between the trial groups:

> The analysis of the primary endpoint dataset you submitted using the prospectively designed statistical test did not demonstrate a statistically significant difference between treatment groups (p=0.195). Thus, even if this were a valid analysis..., the trial failed to demonstrate efficacy on the prospective primary analysis.

The review letter also offered fundamental criticisms of TKT's handling of the study data:

> [T]he process used to select which values to include in the primary analytical dataset introduced unmeasurable bias and is both inappropriate and unacceptable. We thus conclude that there is no valid analysis of the primary endpoint of TKT003.

22. The January 2, 2001 review letter thus contained a detailed and unequivocal statement by the FDA that TKT's pivotal study was a failure, its methodology was flawed, its primary analysis had not demonstrated a treatment effect on pain with statistical significance, and TKT should conduct additional clinical trials if it hoped to obtain FDA approval for Replagal.

TKT's Misleading January 3, 2001 Press Release

23. On January 3, 2001, after the stock market had closed, TKT issued a press release announcing that the FDA had issued its complete review letter. The same day, TKT filed a current report with the Commission on Form 8-K incorporating the press release. Selden actively participated in drafting the press release, approved the final version of the release, and was quoted in it.

24. The January 3, 2001 press release stated that the FDA had asked for additional data and that TKT employees were working to provide the requested information. The press release was materially misleading because, among other things, it did not disclose that, far from just asking for more information, the FDA had informed TKT that the pivotal study failed to achieve its primary objective and had recommended that TKT conduct additional clinical trials. Even so, market reaction to the release was negative. On January 4, 2001, TKT shares closed at $33.25 per share, down 9% from the previous day's close of $36.56 per share.

25. Within days of the January 2001 press release, a senior executive in charge of clinical trials told Selden that the FDA's recommendation to conduct new studies was important enough to disclose. However, Selden dismissed those concerns, explaining that disclosure was not part of the executive's job, and refused to authorize disclosure of the FDA's recommendation.

26. On January 11, 2001, the FDA's negative view was reaffirmed when TKT's outside counsel spoke with a senior FDA official. The official reiterated the FDA's position that the clinical study was a failure and that the FDA wanted another study.

TKT's Misleading Form 10-K Filed on April 2, 2001

27. On April 2, 2001, TKT filed its annual report on Form 10-K for the year ended December 31, 2000. Selden participated in preparing the Form 10-K, and he signed it as the CEO of TKT.

28. The Form 10-K contained the same statements about the FDA's complete review letter that had appeared in the January 3, 2001 press release, plus some additional generic risk disclosures. These statements were materially misleading because, among other things, they failed to correct TKT's prior misstatements about the results of the clinical trials and because they failed to disclose that, far from just asking for more information, the FDA had informed TKT that its pivotal study was a failure and had recommended that TKT conduct additional clinical trials.

29. The Form 10-K also incorporated by reference the company's annual report to shareholders. The annual report included a letter from Selden concerning the Replagal application which stated that TKT employees "worked to provide the FDA the requested data," as if TKT had already satisfied the FDA's request for more information. This statement was materially misleading because, among other things, it failed to disclose that the FDA had told TKT that its pivotal study was a failure and had recommended that TKT conduct additional clinical trials.

30. In a sidebar appearing on the same page as Selden's letter to shareholders, the annual report stated that positive pivotal clinical results for Replagal demonstrated a reduction in pain, again failing to correct the prior misstatements about the results of the clinical trials and omitting to state that, in the FDA's view, the pivotal study's primary analysis was a failure.

April 26, 2001 Meeting with the FDA

31. On April 26, 2001, Selden and several other TKT executives met with the FDA staff to discuss the complete review letter. At the meeting, the FDA staff again stated that TKT had not demonstrated that Replagal was effective for the pain of Fabry disease and that its pain data was uninterpretable. The senior FDA official again characterized the pivotal study as a "failed study", criticized the results of a six-month follow-up study which TKT had recently submitted, criticized TKT's proposal for a new study because it contained the same design flaws as the pivotal study, and said that TKT needed to come up with other alternatives.

32. The TKT executives responded that the company was no longer going to seek FDA approval for Replagal on the basis of effect on pain. Contemporary writings by Selden and TKT's outside FDA lawyer, including correspondence to the FDA, used words such as "surrender," "moot" and "out of the picture" to describe TKT's proposed change in approach to the FDA application.

33. The remainder of the meeting focused on other ways in which Replagal might be approved. The FDA staff left open the possibility that additional clinical data from a study that had not then been completed, or surrogate marker data of the type being proposed by Genzyme for its competing drug, could lead to approval for Replagal on the basis of a predicted clinical benefit for kidney function. However, the FDA staff made clear that, as the agency had previously informed TKT, the company should not expect approval on the basis of the clinical data already submitted.

TKT's Misleading Form 10-Q Filed on May 14, 2001

34. On May 14, 2001, TKT filed its report on Form 10-Q for the quarter ended March 31, 2001. Selden reviewed and approved the Form 10-Q.

35. When describing the status of the FDA application for Replagal, the Form 10-Q repeated the grossly incomplete characterization of the FDA's complete review letter from the January 2001 press release and the April 2, 2001 Form 10-K, stating only that the FDA "requested further explanation in several areas and additional data." These statements were materially misleading because, besides failing to indicate that the FDA's complete review letter had labeled the pivotal study as a failure, TKT failed to report on the April 26, 2001 meeting, at which the FDA had dismissed the additional data submitted by TKT and questioned the methodology for its proposed new study, and at which TKT had admitted that it was no longer seeking approval for Replagal on the basis that it was effective for pain.

TKT's Misleading May 29, 2001 Press Release

36. On May 29, 2001, TKT issued a press release to publicize an article concerning the pivotal study which had been published in the *Journal of the American Medical Society*. Selden approved the final version of the press release, which had been prepared by TKT's head of investor relations.

37. The press release stated that patients receiving Replagal had a clinically significant reduction in pain. As a result, *Bloomberg* reported on June 5, 2001 that Replagal "markedly relieves pain and improves heart and kidney function."

38. The May 29, 2001 press release was materially misleading because it failed to include at least four critical and negative facts: (1) the *p* value for the pivotal study's primary

analysis was 0.19, much worse than the desired level of 0.05 or less and much worse than the 0.02 figure which TKT had misleadingly presented at the October 2000 ASHG conference; (2) the FDA had stated that the pivotal study was a failure; (3) the FDA had recommended additional clinical trials; and (4) based on the FDA's criticisms of its clinical trial results, TKT had informed the FDA that it was no longer seeking approval for Replagal on the basis of effect on pain.

May 30, 2001 Conference Call with the FDA

39. On or about May 30, 2001, several TKT executives, including Selden, had a conference call with the FDA staff to discuss their continuing review of data submitted by TKT. During this call, the FDA staff reaffirmed their position that TKT's data had failed to demonstrate a treatment effect and again recommended that TKT conduct additional controlled trials.

TKT's Misleading Public Filings from June 2001 through May 2002

40. On June 25, 2001, TKT filed with the Commission a Form 8-K updating its risk disclosure. On June 26, 2001, TKT filed with the Commission a prospectus supplement in connection with a public stock offering. Selden as the CEO of TKT had overall responsibility for both filings.

41. The Form 8-K and prospectus supplement contained similar language concerning Replagal. With respect to the FDA application, the supplement stated:

> The FDA letter stated that the data that we had provided was not adequate for approval of our BLA [Biologic License Application, the formal name for the Replagal application] at the time and requested additional information. In response to this letter, we have discussed our BLA with

> the FDA and have submitted additional data to the FDA. We expect that after the FDA has reviewed our additional data, it will either approve the BLA or decline to approve it. If it declines to approve our BLA, the FDA may request additional information, possibly including data from additional clinical trials.

These statements were materially misleading because, rather than merely requesting additional information, the FDA had explicitly informed TKT that the pivotal study was a failure and had recommended that TKT conduct additional clinical trials, and because, in light of the FDA's negative response, TKT had informed the FDA that it was withdrawing its claims about Replagal's effect on pain and was now relying on the drug's potential impact on kidney function as the basis for obtaining FDA approval.

42. TKT's subsequent public filings in 2001, for which Selden had overall responsibility as CEO, were similarly misleading. In the reports on Form 10-Q which it filed for the quarter ended June 30, 2001 (filed on August 14, 2001) and for the quarter ended September 30, 2001 (filed on November 14, 2001), TKT stated that, according to the FDA's complete review letter, "our BLA was not adequate for final approval action at the time of such letter" and "[t]here can be no assurance as to whether or when [the] application ... will be approved by the relevant regulatory authorities." These statements were materially misleading because, as shown above, Replagal's chances for FDA approval were actually much worse than indicated and TKT had withdrawn the primary basis for its application (Replagal's effect on pain).

43. TKT filed a prospectus and a Form 8-K updating risk disclosures in connection with other stock offerings on December 13, 20 and 21, 2001. These, as well as the Form 10-K for the year ended December 31, 2001 (filed on March 29, 2002), the Form 10-Q for the first

quarter of 2002 (filed on May 15, 2002), and the Form 10-Q for the second quarter of 2002 (filed on August 14, 2002), contained substantially the same disclosure, each of which was materially misleading for the reasons set forth in the preceding two paragraphs. Selden had overall responsibility for these filings as CEO of TKT.

Selden's Misleading Statements to Analysts from Fall 2001 to Spring 2002

44. From the fall of 2001 through the spring of 2002, Selden expressed unfounded optimism and failed to disclose material negative information about the Replagal application in response to direct inquiries from stock market analysts during quarterly conference calls. The question of whether the FDA had recommended new or additional studies was raised repeatedly during these calls. Each time, Selden provided evasive answers which gave the impression that the FDA had not recommended additional studies and that FDA approval on the basis of existing data was likely.

45. For example, in an October 29, 2001 conference call to discuss results of the quarter ended September 30, 2001, an analyst twice asked Selden whether the FDA had suggested additional clinical trials. Selden responded:

> At this point, we think the data that we've provided is already sufficient. And, we have spent a fair amount of time – and continue to spend a fair amount of time – discussing that data. And so, at this point, I don't believe additional trials are going to be required. I can't absolutely rule it out though – I just don't think they'll be required. I think that we have a great data package as it is.

These statements were materially misleading because, among other things, Selden failed to disclose that the *p* value for the primary analysis in the pivotal study was 0.19, much worse than the desired level of 0.05 or less, and that the FDA had repeatedly informed TKT that its trials

were a failure, that TKT should conduct additional clinical trials, and that TKT could not expect approval of Replagal based on the existing data. Further, Selden failed to disclose that, in light of the FDA's continued criticism of its pivotal trial data, TKT had informed the FDA that it was dropping its claim that Replagal was effective on pain and was now seeking approval only on the basis of effect on kidney function, a claim that would require continuing clinical trials. Moreover, these statements were far more optimistic than the negative information which Selden had disclosed to the institutional investor at their confidential meeting back in May 2000, and Replagal's chances for FDA approval had not improved since that meeting.

46. In a February 11, 2002 conference call to discuss year-end results, an analyst asked Selden whether any new trials had been initiated at the request of the FDA. Selden responded that "no trials have been initiated on FDA requirements." This statement was materially misleading for the same reasons cited in the preceding paragraph.

47. In April 2002, the FDA informed TKT that it was willing to consider approving Replagal using "surrogate markers," a form of approval that would require continuing clinical trials in order to demonstrate the clinical benefits that TKT had publicly reported it had achieved. However, the FDA requested substantial additional information, making clear to TKT management that FDA approval was not assured, even on this alternative basis.

48. In a May 2, 2002 conference call with analysts to discuss results for the quarter ended March 31, 2002, Selden optimistically stated, "We believe that the approval of Replagal in the U.S. remains a 'when,' not 'if', proposition." When asked for a more detailed description of the FDA discussions, Selden stated that the conversations with the FDA were very reasonable and were getting better and better. These statements were materially misleading because, among

other things, Selden failed to disclose that the FDA had been telling TKT since January 2001 that Replagal could not be approved based on existing data and that, as recently as April 2002, the FDA had made clear that approval was not assured.

Postponement of the September 2002 Advisory Committee Meeting

49. In early summer 2002, the FDA scheduled an advisory committee meeting for September 26-27, 2002 to review the competing applications by TKT and Genzyme. Such meetings are typically the last step before an FDA decision on approval, and the meetings involve committee members, guests and advisors. Briefing materials are usually posted on the FDA's public Website the day before the meeting.

50. The FDA's briefing materials, consistent with all of their prior statements to TKT, harshly criticized TKT's clinical data, particularly the pain data, as well as TKT's methodology and results, and indicated that the FDA staff could not interpret the pain data submitted and could not draw any conclusions with respect to effect on pain. The FDA materials concluded that the purported kidney benefits of Replagal depended entirely on a "physiologically improbable" change occurring entirely during the 24th week of the study, and that other analyses, including the cardiac data, generally showed no treatment effect.

51. On September 11, 2002, TKT's outside attorney wrote to the FDA alleging that four invited advisory committee guest experts were biased. On September 20, 2002, the FDA abruptly cancelled the meeting. As a result, the FDA's negative briefing materials concerning Replagal were not made public at that time. The advisory committee meeting was later rescheduled for January 15-16, 2003.

Public Disclosure in October 2002

52. At no time prior to October 1, 2002 did TKT inform the public that: (1) the *p* value for the primary analysis in the pivotal study was 0.19, much worse that the desired level of 0.05 level or less and much worse than the 0.02 figure which TKT had misleadingly presented at the October 2000 ASHG conference; (2) the FDA had stated that the pivotal study was a failure; (3) the FDA had recommended additional clinical trials; (4) based on the FDA's criticisms of its clinical pain results, TKT had informed the FDA that it was no longer seeking approval for Replagal on the basis of pain relief; and (5) TKT was now relying solely on Replagal's potential impact on kidney function, an impact to be demonstrated through surrogate marker data instead of proven clinical benefits.

53. On October 2, 2002 – after the stock market closed – TKT issued a press release announcing that the FDA found its pain data to be "uninterpretable" and that TKT had therefore withdrawn its claim that Replagal was effective against pain as a basis for seeking approval of Replagal. A few minutes later, Selden held a conference call with investors. He was repeatedly evasive when asked for further detail about the press release. However, he stated that discussions with the FDA leading to the announcement had occurred only during the past month. He also characterized the change in TKT's strategy for FDA approval as "moderate", asserting that TKT had decided "not to use the pain data as a basis for seeking approval *at this time*" (emphasis added). These statements were false because TKT had actually informed the FDA at least eighteen months earlier (in April 2001) that it was no longer seeking approval based on Replagal's effect on pain.

54. The stock market reacted strongly to TKT's disclosure of the major problems with its FDA application for Replagal. On October 3, 2002, TKT shares closed at $12.75 per share, down 61% from the prior day's close of $33.25 per share. Trading volume on October 3 was 22.8 million shares, whereas trading volume during the preceding month was typically less than 500,000 shares per day.

Subsequent Events

55. On January 15-16, 2003, the FDA advisory committee met to consider TKT's application for Replagal. By a vote of 15-0, the committee rejected the application on the basis of demonstrated clinical results. By a vote of 8-7, the committee rejected the application on the basis of surrogate markers, although the committee held out some prospect that the issue could be revisited with additional analysis. The FDA approved Genzyme's competing application, and Genzyme received a seven-year marketing exclusivity for its drug Fabrazyme.

56. Later in January 2003, the TKT board of directors established a committee to investigate certain management issues, including the handling of the Replagal application. In February 2003, Selden resigned as CEO, although he continued to receive an equivalent salary pursuant to a consulting agreement.

57. On January 12, 2004, TKT announced that it was ending its efforts to seek FDA approval for domestic sales of Replagal.

Selden's Sales of Transkaryotic Shares

58. During 2001 and the first half of 2002 – when he knew that he and TKT had disseminated false and misleading information concerning Replagal to the investing public –

Selden sold tens of thousands of shares of TKT stock.

59. On May 8, 2001, Selden sold 20,000 shares at $22.90 per share. This sale was only two weeks after the April 26, 2001 meeting at which the FDA staff had characterized TKT's pivotal study as a "failed study", had criticized the results of TKT's six-month follow-up study, had criticized TKT's proposal for a new study because of its design flaws, and had stated that TKT needed to come up with other alternatives.

60. On September 20-21, 2001, Selden sold 20,000 shares: 10,000 shares at $24.43 per share and 10,000 shares at $25.05 per share. These sales were one month after TKT had filed a materially misleading Form 10-Q which failed to disclose that the FDA had told TKT that the pivotal trial was a failure and had recommended that TKT conduct additional clinical trials, and which also failed to disclose that, in light of the FDA's negative response, TKT was no longer basing its application on Replagal's effect on pain and was relying instead solely on Replagal's potential impact on kidney function.

61. On November 1, 2001, Selden sold 30,000 shares at $37.07 per share. This sale was one month after TKT had filed another materially misleading Form 10-Q which failed to disclose that the same negative information.

62. On February 14, 2002, Selden sold 20,000 shares at $37.33 per share. This sale was three days after a conference call with analysts in which Selden had once again concealed the FDA's recommendation that TKT conduct additional clinical trials and TKT's decision to withdraw its claim that Replagal had an effect on pain.

63. As demonstrated by the market reaction to the negative information about Replagal that was ultimately disclosed on October 2, 2002, the false and misleading information

previously in the public realm had kept TKT's stock price artificially inflated since at least October 2000. Thus, Selden benefitted by selling TKT shares at artificially inflated prices before the negative news was made public.

64. Based on the closing price of TKT stock after the first day of trading after the negative news had been announced on October 2, 2002, Selden was unjustly enriched in the amount of $1,664,400.

FIRST CLAIM FOR RELIEF
(Violation of Section 10(b) of the Exchange Act and Rule 10b-5)

65. The Commission repeats and realleges paragraphs 1 - 64 above.

66. As set forth above, Selden made direct statements to investors and market participants, authorized other TKT employees to make statements to the public concerning Replagal, exercised control over all significant disclosure decisions by TKT, signed TKT's materially misleading Forms 10-K for 2000 and 2001, authorized TKT's offerings of securities using prospectuses that were materially misleading, and offered and sold his own shares to public investors. He knew or was reckless in not knowing that these filings and other public statements were materially misleading because, among other things, they contained false and misleading statements regarding Replagal's clinical results and the FDA application and they omitted material information necessary to make statements made not misleading.

67. By reason of the foregoing, Selden, directly or indirectly, acting intentionally, knowingly or recklessly, by use of the means or instrumentalities of interstate commerce or of the mails, in connection with the purchase or sale of securities: (a) employed devices, schemes or artifices to defraud; (b) made untrue statements of material fact or omitted to state a material fact

necessary to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in acts, practices or courses of business which operated as a fraud or deceit upon certain persons, including purchasers or sellers of TKT's securities.

68. As a result, Selden violated Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5], and his violations involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements and resulted in substantial losses or significant risk of substantial losses to other persons, within the meaning of Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)].

SECOND CLAIM FOR RELIEF
(Violation of Section 17(a) of the Securities Act)

69. The Commission repeats and realleges paragraphs 1- 68 above.

70. As set forth above, Selden made direct statements to investors and market participants, authorized other TKT employees to make statements to the public concerning Replagal, exercised control over all significant disclosure decisions by TKT, signed TKT's materially misleading Forms10-K for 2000 and 2001, authorized TKT's offerings of securities using prospectuses that were materially misleading, and offered and sold his own shares to public investors. He knew or was reckless in not knowing that these filings and other public statements were materially misleading because, among other things, they made false and misleading statements regarding Replagal's clinical results and the FDA application, and that material information necessary to make statements made not misleading was omitted.

71. By reason of the foregoing, Selden, directly or indirectly, acting intentionally, knowingly or recklessly, by use of the means or instruments of transportation or communication

in interstate commerce or by the use of the mails, in the offer or sale of securities: (a) employed devices, schemes or artifices to defraud; (b) obtained money or property by means of untrue statements of material fact or omissions to state material facts necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or (c) engaged in transactions, practices or courses of business which operated or would operate as a fraud or deceit upon certain purchasers, including purchasers of TKT's securities.

72. As a result, Selden violated Section 17(a) of the Securities Act [15 U.S.C. §77q(a)], and his violations involved fraud, deceit, or deliberate or reckless disregard of regulatory requirements and directly or indirectly resulted in substantial losses or significant risk of substantial losses to other persons, within the meaning of Section 20(d) of the Securities Act [15 U.S.C. §77t(d)].

THIRD CLAIM FOR RELIEF
(Aiding and Abetting TKT's Violations of
Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13)

73. The Commission repeats and realleges paragraphs 1- 72 above.

74. TKT's annual reports to the Commission on Form 10-K for 2000 and 2001, its quarterly reports to the Commission on Form 10-Q for the first quarter of 2001 through the second quarter of 2002, and certain reports of current events filed as part of Forms 8-K materially misstated facts, and omitted to state material facts necessary to make statements made not misleading, relating to Replagal and the FDA application process. As a result, TKT violated Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13].

75. As set forth above, Selden signed certain of TKT's materially misleading filings with the Commission and substantially participated in preparing each of those public filings.

76. By reason of the foregoing, Selden provided knowing and substantial assistance to TKT's filing of materially misleading reports to the Commission.

77. As a result, Selden aided and abetted TKT's violations of Section 13(a) of the Exchange Act and Rules 12b-20, 13a-1, 13a-11 and 13a-13.

PRAYER FOR RELIEF

WHEREFORE, the Commission requests that this Court:

A. Enter a permanent injunction restraining Selden and each of his agents, servants, employees and attorneys and those persons in active concert or participation with them who receive actual notice of the injunction by personal service or otherwise, including facsimile transmission or overnight delivery service, from directly or indirectly engaging in violations of:

1. Section 10(b) of the Exchange Act [15 U.S.C. §78j(b)] and Rule 10b-5 thereunder [17 C.F.R. §240.10b-5];

2. Section 17(a) of the Securities Act [15 U.S.C. §77q(a)]; and

3. Section 13(a) of the Exchange Act [15 U.S.C. §78m(a)] and Rules 12b-20, 13a-1, 13a-11 and 13a-13 thereunder [17 C.F.R. §§240.12b-20, 240.13a-1, 240.13a-11 and 240.13a-13];

B. Order Selden to disgorge all unlawful benefits received, including his unjust enrichment from his sales of TKT shares during the relevant period and, as appropriate, salary, bonus and other compensation received from TKT;

C. Order Selden to pay an appropriate civil penalty pursuant to Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. §78u(d)(3)];

D. Enter an order, pursuant to Section 20(e) of the Securities Act [15 U.S.C. §77t(e)] and Section 21(d)(2) of the Exchange Act [15 U.S.C. §78u(d)(2)], barring Selden from serving as an officer or director of any issuer required to file reports with the Commission pursuant to Sections 12(b), 12(g) or 15(d) of the Exchange Act [15 U.S.C. §§78l(b), 78l(g) and 78o(d)];

E. Retain jurisdiction over this action to implement and carry out the terms of all orders and decrees that may be entered; and

F. Award such other and further relief as the Court deems just and proper.

Respectfully submitted,

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Dated: September 1, 2005

TAB B

Exhibit A

Schedule A Request (paraphrased)	**Negotiated FDA Production**	**FDA's Proposed Timing**[1]
1. All FDA documents relating to FDA's consideration of surrogate endpoints for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, including, but not limited to, all: A) internal FDA correspondence and documents relating to Dr. Selden, TKT, Replagal, the Fabrazyme Biologic License Application ("BLA"), or any Fabrazyme-related Investigational New Drug Application ("IND"); and B) materials from the Jan. 2003 FDA advisory committee meeting relating to Replagal or Fabrazyme. FDA will not produce: - documents submitted by TKT - Fabrazyme documents relating exclusively to chemistry, manufacturing, or controls ("CMC") - Fabrazyme documents generated after 4/23/03	A) FDA has an estimated 15,375 pages of potentially responsive documents, requiring 768 hours of review time. Anticipated production date uncertain.[2] B) FDA has an estimated 3,500 pages of potentially responsive documents, requiring 175 hours of review time. Anticipated production date uncertain.
2. All FDA documents relating to FDA's consideration of dual approval for Replagal and/or Fabrazyme.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 4, 6, and 7.	See timing for Schedule A request 1.
3. Every complete response letter ("CRL") issued by the FDA's Center For Biologics Evaluation And Review ("CBER") from 1987 to the present.	**Open Issue, see Ex. B infra.**	If this request is narrowed to include every CRL issued by CBER in 2000 and 2001, subject to the criteria listed below in Exhibit B, FDA has identified 30 CRLs responsive to this request, totaling an estimated 393 pages and requiring 20 hours of review time. Anticipated production date of 10/3/06.
4. All documents relating to Replagal.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 6, and 7.	See timing for Schedule A request 1.
5. All documents relating to TKT but not to Replagal.	No production necessary.	N/A

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
6. All documents relating to Dr. Selden.	FDA will produce all responsive documents, a portion of which are also expected to be responsive to Schedule A requests 1, 2, 4, and 7.	See timing for Schedule A request 1.
7. All documents relating to Fabrazyme through 4/24/03.	FDA will produce all: A) CRLs sent to Genzyme regarding Fabrazyme; B) Genzyme responses to Fabrazyme CRLs, except portions relating exclusively to CMC; C) correspondence between Genzyme and FDA, in addition to CRLs and CRL responses, relating to Fabrazyme; D) portions of the original Fabrazyme BLA or any Fabrazyme-related IND relating to clinical, safety, efficacy and/or clinical trials; E) internal FDA correspondence and documents relating to the Fabrazyme BLA or any Fabrazyme-related IND, except documents generated after 4/23/03; and F) materials from the Jan. 2003 FDA advisory committee meeting relating to Fabrazyme, except the meeting transcript and materials submitted by TKT.	A) FDA has already identified an estimated 25 pages of responsive documents, requiring 1.25 hours of review time. Anticipated production date of 9/29/06. B) FDA has an estimated 75 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 7,500 to 37,500 pages) of potentially responsive documents, requiring between 375 and 1,875 hours of review time. Anticipated production date uncertain. C) Anticipated production date of 12/31/06. D) FDA has an estimated 46 volumes (each vol. is expected to contain between 100 and 500 pages for a total of approximately 4,600 to 23,000 pages) of potentially responsive documents, requiring between 230 and 1,150 hours of review time. This estimate does not include any documents from any Fabrazyme-related INDs, which may contain even more potentially responsive documents. Anticipated production date uncertain. E) See timing for Schedule A request 1. F) See timing for Schedule A request 1.
8. All documents relating to the SEC lawsuit or any other actual/possible lawsuit involving TKT or Replagal.	FDA will produce all responsive documents, except: - documents submitted by TKT - documents unrelated to Replagal	FDA has an estimated 500 pages of potentially responsive documents. Anticipated production date of 12/31/06.

Exhibit A

Schedule A Request (paraphrased)	Negotiated FDA Production	FDA's Proposed Timing[1]
9. All guidelines for CBER review of BLAs, INDs, trials, protocols, etc.	FDA will produce any internal FDA manuals, guidelines or templates available for reference or use, as of January 1, 1996 or later, in connection with the review of a BLA or IND.	FDA has an estimated 41,000 pages of responsive documents, requiring 2050 hours of review time. Anticipated production date uncertain.
10. Record retention schedules under 21 C.F.R. § 20.23(c)	FDA will produce its Headquarters Record Control Schedule, last updated on 12/31/89, which FDA represents was the applicable record retention schedule for the period 1990 to present.	FDA has already collected 104 pages of responsive documents. Anticipated production date of 9/1/06.
11. All documents relating to the dissolution/potential dissolution of CBER.	No production necessary.	N/A
12. Any proposed or final documents relating to guiding public disclosure of BLA status.	FDA will produce any internal FDA proposals or draft guidelines relating to the public disclosure, by the applicant, of the status of the applicant's BLA.	FDA's preliminary search has not identified any documents responsive to this request.
13. All documents relating to joint FDA/SEC coordination.	FDA will produce all correspondence and communications, and all documents reflecting, memorializing or referring to any correspondence or communications, between FDA and the SEC relating to Dr. Selden, TKT, Replagal, or any joint FDA/SEC efforts to enhance inter-agency cooperation.	In addition to those documents identified as responsive to Schedule A Request 8, FDA has an estimated additional 1000 pages of potentially responsive documents. Anticipated production date of 12/31/06.

[1] Productions will be made by four different components within FDA on a rolling basis, and the anticipated production date is the final date by which the production of this category of documents will be completed by all FDA components. Estimates of the number of FDA staff hours necessary for production are based on an estimated 3 minutes per page for review and redaction of documents. FDA will provide a privilege log no later than 90 days after the completion of the production of each category of documents described above.

[2] See Exhibit B, Open Issue 1.

TAB C

Exhibit B

Issue #1: Timing of FDA production of documents

FDA's position:

FDA is unable to provide the Court with an exact date for its completion of production of all documents responsive to Subpoena Requests 1, 2, 4, 6, 7(B), (D)-(F), and 13 because FDA's initial search has identified an estimated 120,375 pages of documents that are potentially responsive to these requests. Presently, FDA estimates that it will take two months to collect and organize these documents and twenty months to complete the review, redaction, and supervisory review of the redactions (assuming three full-time employees are assigned to work on this project for six to eight hours per day, and spend approximately 3 minutes per page for review and redaction). Thus, based on an estimated volume of up to 120,375 pages of documents, the total time to production is expected to be twenty-two months from the day the search begins. FDA will make every effort to adhere to this timeframe. If less than 120,375 pages of documents are ultimately identified, or if Dr. Selden is able to further refine his request as outlined below, the review and redaction times can be reduced proportionately (e.g., if only 71,975 pages are identified, the time to production could be reduced to about thirteen months). If more than 120,375 pages are ultimately identified, the review and redaction times would be increased (e.g., if 140,000 pages are identified, the time to production would increase to twenty-seven months).

With respect to Subpoena Request 7(B), FDA has immediately available the three CRLs that FDA sent to Genzyme relating to its Fabrazyme product, as well as the table of contents for Genzyme's responses to these three CRLs. With respect to Subpoena Request 7(D), FDA has immediately available the table of contents for the portions of the original BLA for Fabrazyme that relate to clinical safety and efficacy, as well as a Genzyme-prepared overview of the clinical safety and efficacy portion of the original BLA for Fabrazyme. In the interest of prioritizing the

Exhibit B

FDA resources that must be marshaled to produce documents pursuant to this request, FDA proposes to provide Dr. Selden with these tables of contents and overviews so that Dr. Selden can identify the order of priority for production of the documents that are responsive to this request. If Dr. Selden is willing to narrow his request using these materials, the time required by FDA for the production of the documents he seeks could be significantly reduced.

Dr. Selden's Position:

The Court in the District of Massachusetts has already extended the pre-trial calendar in SEC v. Selden by six months to accommodate FDA's delay in responding to the subpoenas. The current schedule now requires all written discovery to be completed by October 30, 2006, with all depositions to be completed by end of February 2007. Nevertheless, the FDA now says that it will need another 22 months -- or until the middle of 2008 -- to complete the production. Surely this could not be the "prompt" FDA response that the Court had in mind when granting Dr. Selden's motion to compel (see Memorandum Opinion, Docket Entry No. 19 at 7 n.7), given that it would render the subpoenas essentially meaningless. Further, it would deny Dr. Selden a fair defense against a government enforcement action brought with the assistance of FDA itself. Lastly, FDA's proposed 22-month schedule is not defensible because it does not jibe with the realities of litigation document review. For example, under FDA's estimate, it will take six weeks for one person to review and process a single box of documents.[3] Even a conservative estimate of the review time for a box of documents in a complex litigation would be no more than 4-5 days per box, a period that can be accelerated with additional resource commitment or,

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[3] This figure is derived as follows: The FDA estimates a total production of 120,375 pages of documents. One standard size file box (or "banker's box") can hold approximately 2,500-3,000 pages of documents. FDA says it will take three people 22 months to complete this production, meaning that one person will need 22 months to complete approximately 13-16 boxes, or 6-7 weeks per box, per person.

Exhibit B

specific to FDA, a waiver of the deliberative process privilege (see Issue #3, below). Thus, the Court should order FDA to comply with the subpoenas on an accelerated basis by October 30, 2006, the end of the written discovery period in SEC v. Selden.

Issue #2: Request No. 3[4]

(A) Time range for CRLs to be produced

FDA's position:

FDA has agreed to produce every CRL issued by CBER between January 1, 2000 and December 31, 2001, excluding those CRLs issued for products that were never approved, those CRLs sent in response to Biologic License Application ("BLA") supplements rather than original applications, and those CRLs issued for products for which user fees were not collected. Applying these criteria to narrow Dr. Selden's request ensures that only CRLs issued for products with applications that are similar to Replagal's application will be produced. The January 1, 2000 and December 31, 2001 time period proposed by FDA will result in the production of all such CRLs for the year proceeding and the year following FDA's issuance of the Replagal CRL, which was issued in January 2001.

FDA has identified 30 CRLs for products fitting the above criteria that were issued during the relevant two-year time period. This search required twelve hours of FDA staff time, the review and redaction of these CRLs will require an additional 20 hours, and production

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[4] Request No. 3 of Schedule A calls for "[e]very complete response letter ('CRL') issued by the FDA's Center For Biologics Evaluation And Review ('CBER') from 1987 to the present." The SEC v. Selden case concerns the Complete Response Letter of Transkaryotic Therapies, Inc. ("TKT"). In that action, the SEC alleges Dr. Selden fraudulently misrepresented what the CRL said and meant. Complete Response Letters (sometimes referred to as "Complete Review Letters" or "CRLs") are "issued [by CBER] when the complete review indicates that there are deficiencies remaining that preclude the approval of the application or supplement at that time. The Complete Response Letter will: Summarize all of the deficiencies remaining, and [w]here appropriate, describe actions necessary to place the application/supplement in a condition for approval." CBER Manual Of Standard Operating Procedures And Policies ("SOPP") 8405, version #4 (eff. Sept. 20, 2004). The definition of CRL has also been revised several times during the relevant period.

should be complete by 10/3/06. If FDA were ordered to produce every CRL issued by CBER during the 18-year period sought by Dr. Selden, the resulting massive undertaking would require years of FDA staff time to search for, organize, review, redact, and produce the estimated 400,000 pages of responsive documents. As FDA has consistently maintained, such a request is "unduly burdensome and over broad" because it seeks documents "more than 18 years old," encompasses "many thousands of pages," and would thus "further strain FDA's already overburdened document production capacity." FDA Motion to Quash at 4, 8.

Dr. Selden's Position:

FDA's refusal to produce CRLs beyond the years 2000 and 2001 is a new position that FDA took only in the last three weeks. Nevertheless, Dr. Selden is willing to agree to a protocol that would make the production non-burdensome on FDA (see 2.B., below), but FDA has not been willing to discuss this option.

(B) Open issue regarding production of CRLs for unapproved products

FDA's position:

FDA may not produce any CRLs for products that have not been approved because its regulations forbid FDA from releasing any information regarding unapproved BLA's. See 21 C.F.R. § 601.51(b) ("The existence of a biological product file will not be disclosed by the Food and Drug Administration before a biologics license application has been approved unless it has previously been disclosed or acknowledged."). The very existence of a BLA for a product that has not yet received FDA approval may be considered trade secret and confidential commercial information ("CCI"), and FDA's release of such information could constitute a violation of both the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(j), and the Federal Trade Secrets Act, 18 U.S.C. § 1905, both of which carry individual criminal liability. See Jerome Stevens Pharms.

Exhibit B

v. FDA, 319 F. Supp. 2d 45 (D.D.C. 2004), aff'd in part, rev'd in part, 420 F.3d 1249 (D.C. Cir. 2005) (seeking $1.345 billion in damages for FDA's alleged release of trade secret and CCI contained in a new drug application).

Neither of these statutes, nor FDA's regulations, provide for an "attorneys' eyes only" exception for the release of trade secret or CCI. Should the court order FDA to produce the CRLs that Dr. Selden seeks, FDA would need to alert the hundreds of entities to whom these unapproved CRLs were issued during this 18-year period to permit them to intervene in the present action to defend their proprietary information. See 21 C.F.R. § 20.48 (requiring FDA to give notice to "a person who will be affected by a proposed disclosure of data or information contained in Food and Drug records" to permit them "to institute suit in a United States District Court to enjoin release of the records" and prohibiting FDA from "disclos[ing] the records involved until the matter and all related appeals have been concluded").

Dr. Selden's Position:

FDA's stated position derives from a premise not at issue here; namely, that Dr. Selden is seeking the public disclosure of confidential information. Not so. Dr. Selden's interest in the materials is limited to defending himself in the government enforcement action; and FDA regulations specifically provide a process for limited disclosure of non-public information in connection with court proceedings:

> Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative proceedings pursuant to parts 10, 12, 13, 14, 15, 17, and 19 of this chapter or court proceedings, where data or information are relevant. The Food and Drug Administration will take appropriate measures, or request that appropriate measures be taken, to reduce disclosure to the minimum necessary under the circumstances.

Exhibit B

21 C.F.R. § 20.86 ("Disclosure in administrative or court proceedings") (emphasis added). Further, contrary to FDA's blanket assertion that it cannot produce any non-public information without an extensive notice period and the exhaustion of all legal remedies by those affected, FDA regulations contemplate production subject to measures that can be adopted "to reduce disclosure to the minimum necessary under the circumstances."

Consistent with the above, Dr. Selden is willing to agree to the entry of a protective order that would protect the confidentiality of the CRLs while permitting him limited use for purposes of his defense. However, to date FDA has refused to engage in any dialogue on what measures FDA believes are appropriate. Dr. Selden has already offered the following: first, Dr. Selden will agree to an order precluding the use of any non-public information outside of the SEC v. Selden litigation; second, Dr. Selden will agree to a protocol that limits CRL access to "attorneys' eyes only"; and third, Dr. Selden will agree that if information from the CRLs is referred to (by an expert, for example), such reference will not include the applicant name or product; but rather refer to a numerical identifier (e.g., "CRL #1").

Issue #3: FDA Assertion Of "Deliberative Process" Privilege Over Entire Production

FDA's position:

FDA is not intending to assert the deliberative process privilege over every document responsive to the subpoena. Indeed, Selden correctly asserts that FDA waived its deliberative process privilege with respect to a limited number of documents provided to the SEC in a completely unrelated matter, but the circumstances of that decision differed markedly from those in the present action. For instance, FDA disclosed the documents at issue in that case to the SEC pursuant to FDA regulations that permit the inter-agency sharing of documents. See 21 U.S.C. § 20.85.

Exhibit B

With respect to any assertion of the deliberative process privilege, FDA does not believe that this issue is ripe for decision at this point in the litigation. FDA will not agree to summarily waive the deliberative process privilege before the agency has had a chance to assert the privilege in regards to specific documents and provide the Court with the reasoning for the assertion on a privilege log. FDA believes, however, and has consistently maintained, that Dr. Selden's requests seek "disclosure of information that is or contains . . . pre-decisional, and/or agency deliberative process information that is protected from disclosure under the applicable laws, regulations, or privileges." See FDA November 9, 2005 Letter (Attached to Selden's Motion to Compel Memo as Attachment D). A consistent policy of withholding information subject to the deliberative process privilege encourages full and frank discussion among FDA decisionmakers. See 21 C.F.R. § 20.62 (permitting intra-agency writings to be withheld from public disclosure); see also Dep't of Interior v. Klamath Water Users Protective Ass'n, 532 U.S. 1, 8-9 (2001) ("The deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news, and its object is to enhance 'the quality of agency decisions,' by protecting open and frank discussion among those who make them within the Government.").

Moreover, FDA's decision to withhold privileged information in the present litigation must be analyzed anew, within the confines of the present action. See In re Sealed Case, 121 F.3d 729, 737-738 (D.C. Cir. 1997) ("Each time the deliberative process privilege is asserted the district court must undertake a fresh balancing of the competing interests, taking into account factors such as the relevance of the evidence, the availability of other evidence, the seriousness of the litigation, the role of the government, and the possibility of future timidity by government employees.") (internal citation and quotation marks omitted). The Court's failure to perform a

Exhibit B

"fresh" review of FDA's assertion of the deliberative process privilege would not only negatively impact frank discussions among agency employees, but would also be a strong disincentive for the agency to ever agree to a waiver of the privilege, regardless of the circumstances. Because FDA has not to date asserted the deliberative process privilege in a concrete setting, the issue is not ripe for judicial consideration.

Dr. Selden's Position:

Until very recently, FDA stated that it was contemplating a waiver of the "deliberative process" privilege in this action as it did in the virtually identical SEC v. Biopure action. However, it now says it will not waive the privilege, but that it is premature to discuss its decision in court. FDA's denial of Dr. Selden's request is manifestly ripe for the Court's decision. For several reasons, FDA's decision is both arbitrary and unreasonable.

First, as recently as June 28, 2006, the FDA agreed to waive the privilege, in its entirety, in a virtually identical pending litigation in the District of Massachusetts also brought by the SEC and involving the same regulatory branch of FDA. See SEC v. Biopure Corp., et al., Civ. No. 05-11853-PBS (D. Mass., filed Sept. 15, 2005). There is no sound basis for denying Dr. Selden the same. For example, FDA's only stated reason for asserting the privilege in this case in contrast to Biopure is that the Biopure request came under 21 C.F.R. § 20.85, which provides for the inter-agency sharing of information. See FDA's Position, above. However, both FDA and the SEC have already agreed to use § 20.85 in this case, the same procedure used in Biopure, to request this information from FDA, thus rendering FDA's sole distinction non-existent.

Second, the FDA's only stated justification for asserting the privilege -- that it would "negatively impact frank discussions among agency employees" -- is inapplicable in this case

Exhibit B

because Dr. Selden is not seeking to disclose FDA information to the public, and is willing to agree to a protective order that expressly precludes it.

Third, the effect of the FDA's position would be to eviscerate perhaps the most important reason the subpoenas were issued in the first place; namely, to obtain an understanding of the FDA's own reactions and interpretations of its discussions with the company, Dr. Selden, and the product application.

Issue #4: Depositions of FDA employees

FDA's position:

The subpoenas served upon FDA by Dr. Selden in the present action also requested the depositional testimony of the FDA and the CBER records custodians. Dr. Selden has informed FDA that he seeks such testimony in order to authenticate the records produced by FDA pursuant to these subpoenas. In lieu of these depositions, FDA proposes to authenticate its records via Rule 902 of the Federal Rules of Evidence, consistent with FDA's standard practice when providing documents for use in third-party litigation. see 21 C.F.R. § 20.3 (providing for the certification and authentication of FDA records).

Dr. Selden now seeks to impermissibly expand the present action to encompass his demands for the testimony of four FDA scientists. Such testimony was requested by Dr. Selden pursuant to FDA's Touhy regulations in a letter dated March 29, 2006, See 21 C.F.R. § 20.1, well after the instant litigation was begun. Thus, this request is not part of the current case. After carefully considering this request, FDA permitted Dr. Selden to obtain the testimony of Dr. Walton, the FDA scientist who was previously deposed by the SEC. See FDA Letter dated June 30, 2006. FDA refused to grant Dr. Selden's request for the testimony of the three remaining

Exhibit B

scientists, citing, among other concerns, "FDA's limited resources and the vast number of requests the agency receives for its personnel to testify."

As this Court has already acknowledged, these "subpoenas for testimony are not at issue here." Memorandum Opinion, Aug. 16, 2006, p.3 n.2. FDA's response to Dr. Selden's request for testimony pursuant to FDA's Touhy regulations may only be challenged by Dr. Selden under an arbitrary and capricious standard of review in an action under the Administrative Procedure Act ("APA"). Far from being a "meaningless gesture" as Dr. Selden contends below, such a requirement is well established by the longstanding precedent of this Circuit. See Houston Bus. Journal, Inc. v. Office of the Comptroller, 86 F.3d 1208, 1212 n.4 (D.C. Cir. 1996) (directing third-party litigant to "proceed under the APA, and the federal court will review the agency's decision not to permit its employee to testify under an 'arbitrary and capricious' standard").

Dr. Selden's Position:

Referenced by the Court in its Aug. 16, 2006 Memorandum Opinion (see p. 3 n.2), the testimony of FDA employees Karen Weiss, Duane Rieves and James Kaiser -- which Dr. Selden requested pursuant to FDA's "Touhy" regulations -- are central to his defense and he objects to FDA's refusal to make them available.

The only stated basis for FDA's denial of the testimony is that it would be "duplicative" of Dr. Walton. (FDA's reference above to "other concerns" having been identified in the letter is misleading. The letter specifically stated that it was denying Dr. Selden's request on the basis of the supposed "duplicative" nature of the testimony.) FDA's position is demonstrably false, as Dr. Selden has already communicated to FDA.

Further, with respect to any burden on FDA, Dr. Selden is willing to conduct the depositions during off hours and at any location. A similar procedure was approved by the Court

Exhibit B

for FDA depositions in In re: Vioxx Products Liability Litig., No. MDL 1657, 2006 WL 784878, *12 (E.D. La. Mar. 15, 2006).

Finally, FDA's suggestion of Dr. Selden bringing a separate APA action for relief is, with all due respect, a meaningless gesture under these particular circumstances; where there is an ongoing enforcement action brought by the SEC with the assistance of FDA (including the FDA's permission of "off the record" interviews by SEC of several FDA employees), and is now heading for trial.

Issue #5: Payment of costs for production of FDA documents

FDA's position:

FDA intends to renew its request that Selden be responsible for the significant costs associated with responding to his voluminous subpoena requests, which FDA estimates will require it to dedicate thousands of staff hours in order to produce over 120,000 pages of responsive documents. See Fed. R. Civ. P. 45(c)(2)(B) ("[A]n order to compel production shall protect any person who is not a party . . . from significant expense resulting from the inspection and copying command."). In Northrop Corp. v. McDonnell Douglas Corp, the D.C. Circuit instructed courts to "fully recognize the burden of imposing on a non-party the effort and expense of discovery, particularly when the expense will be borne by the taxpayers." 751 F.2d 395, 407 (D.C. Cir. 1984); see also Linder v. Calero-Portocarrero, 251 F.3d 178, 182 (D.C. Cir. 2001) (concluding that "fee shifting was mandatory" under Rule 45 and requiring the requestor to bear all of the government's nearly $200,000 in costs).

If Dr. Selden's production was being conducted in response to a FOIA request rather than pursuant to a subpoena, the search and review charges would be $40.00 per hour for mid-grade employees, and duplication costs would be $0.10 per page based on the current fee schedule.

Exhibit B

See 21 C.F.R. § 20.45. Based on an estimated volume of up to 120,375 pages of documents and the assignment of three full-time, mid-grade employees for 6 hours per day for twenty-two months, the duplication costs would be approximately $12,000 and the search and review charges would be approximately $317,000.

Dr. Selden's Position:

Dr. Selden, a private citizen, is being accused of fraud by the federal government in an enforcement action that almost certainly would not have been brought without the assistance of FDA. The FDA's involvement in this case stems back to the earliest phases of the SEC's investigation. Having supplied critical assistance to the SEC, including "off the record" interviews of key witnesses, the FDA now wants Dr. Selden to bear the burden and expense of seeking discovery from the very agency that is behind the lawsuit against him. This is unfair and inappropriate.

TAB D

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

SECURITIES AND EXCHANGE COMMISSION,
Plaintiff,

vs.

RICHARD B. SELDEN,
Defendant.

CA No. 05-11805-NMG

BEFORE: THE HONORABLE NATHANIEL M. GORTON

STATUS CONFERENCE

John Joseph Moakley United States Courthouse
Courtroom No. 4
One Courthouse Way
Boston, MA 02210
Thursday, September 28, 2006
3:18 P.M.

Cheryl Dahlstrom, RMR
Official Court Reporter
John Joseph Moakley United States Courthouse
One Courthouse Way, Room 3209
Boston, MA 02210
Mechanical Steno - Transcript by Computer

APPEARANCES:

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SKADDEN, ARPS, SLATE, MEAGHER & FLOM
By: Thomas J. Dougherty, Esq., and
Justin J. Daniels, Esq.
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On behalf of the Defendant.

P R O C E E D I N G S

THE CLERK: Civil Action 05-11805, Securities and Exchange Commission vs. Richard Selden. Counsel please identify themselves for the record.

MR. HUNTINGTON: Good afternoon, your Honor. Frank Huntington and David Butler for the Securities and Exchange Commission.

THE COURT: Good afternoon, Mr. Huntington and Mr. Butler.

MR. DOUGHERTY: Good afternoon, your Honor. Thomas Dougherty and Justin Daniels for Richard Selden.

THE COURT: Mr. Dougherty and Mr. Daniels for Mr. Selden, good afternoon.

It's my understanding that the real party in interest to these hearings is not present but, rather, down in Washington, D.C.; is that fair to say, Mr. Dougherty?

MR. DOUGHERTY: Yes.

THE COURT: I've read the papers and the background of this matter and am, I guess, equally concerned with the district judge in the District of Columbia that you're not getting sufficient cooperation from the Food and Drug Administration. I would ask your opinion as to whether an order of this court as opposed to an order from the district court in the District of Columbia would be beneficial.

MR. DOUGHERTY: I don't know. My concern would be,

without the FDA here, I don't want to characterize or in any way, you know, criticize the FDA. I just don't.

THE COURT: I understand.

MR. DOUGHERTY: And the SEC has been very helpful to us in our efforts.

THE COURT: What about an order to the Food and Drug Administration to appear in this court to show cause why it should not be held in contempt if it is unable to produce documents for a citizen within 22 months of request?

MR. DOUGHERTY: We would certainly support that, your Honor.

THE COURT: Is it your judgment that this court has jurisdiction over the Food and Drug Administration to make such an order?

MR. DOUGHERTY: Yes, certainly. The FDA certainly reaches into this venue.

THE COURT: But you are presently engaged in a miscellaneous action against the Food and Drug Administration in the District of Columbia.

MR. DOUGHERTY: Yes. And I wouldn't want to do -- I wouldn't want to suggest anything without coordination with the district court there. I know from other experiences -- indeed, one that's very parallel to this -- if there were a way to have this court coordinate with that court the order to show cause in either venue, the ultimate resolution in either venue. And

if it were that the FDA's position that they're not subject to jurisdiction here, I suppose they could raise that as well.

THE COURT: Well, the trouble with that is that United States District Courts are not in the habit of calling up each other and coordinating their efforts. We like to think that we operate independently but only on the basis of the jurisdiction that we have. That's why I ask you the question, whether I have jurisdiction.

MR. DOUGHERTY: Well, I certainly could -- we already have pending in the District of Columbia a request for follow-up conference there. I could bring a parallel action here against the FDA in the hope that one way or the other --

THE COURT: I'll tell you. Go ahead. I didn't want to interrupt you.

MR. DOUGHERTY: Just --

THE COURT: I would be inclined, if I have jurisdiction, to compel somebody, whether it's the Boston representative of the Food and Drug Administration or the director of the Food and Drug Administration in Washington, D.C., to appear in this court to explain to me why it should take 22 months to produce documents in a matter that is time-sensitive and in which the documents need to be had.

We wouldn't put up with this from a private litigant. And I don't see -- at least last I heard, the government works for the people and not the other way around. I don't see why

such an order shouldn't be, (a), entered and, (b), complied with.

MR. DOUGHERTY: And if the mechanics for that, your Honor, were to bring an action that we would file related to this and name the representative --

THE COURT: I can't tell you the procedure to follow. I can tell you what I'm inclined to do if I have jurisdiction.

MR. DOUGHERTY: And we will be just as energetic on that wavelength as I think we've tried to convey on the other.

THE COURT: It seems to this Court that you have been energetic in trying to get that discovery. I don't think you can be faulted, having gone out the month after the last -- the scheduling conference and commenced an effort that has now gone on for -- what, 11 or 12 months?

MR. DOUGHERTY: Yeah. Part of our position is, if there had been a B track, as I would call it, that the FDA -- it's not a criticism, but as a matter of fact, if they had sort of started then on the alternative that perhaps they were incorrect, just as any litigant would, we would be actually further along.

THE COURT: Yeah. Again, I would ask the director how many employees there are in the Food and Drug Administration. And if it takes one of those 12,000, or however many there are, six or seven weeks to sit somewhere and compose this box of information that is relevant to this case, then that will be

the order, that he take that six or seven weeks and sit down in a room and produce the documents.

I am sympathetic with trying to obtain discovery from mega bureaucracies, and I do not think that there's a good excuse for the conduct that is -- at least from this one-sided story that I have to this point.

Does the Securities and Exchange Commission have a position in this regard? Mr. Huntington.

MR. HUNTINGTON: Your Honor, thank you. It's complicated. We have tried to help as best we could.

THE COURT: I understand that you have.

MR. HUNTINGTON: And I appreciate Mr. Dougherty's reference to that, because we really have tried to smooth things along.

There is a concern on our part about the scope of what the defense is asking for. And I'm not sure -- if between your efforts and the efforts of the judge in the District of Columbia, if they could persuade the FDA to produce everything that's been sought much sooner, then I wouldn't even worry about raising the issue.

If that's not possible, at some point down the road, we may have a disagreement as to whether everything that the defense is looking for is necessary to really defend this case. We're not ready to argue that today.

THE COURT: There's always room for compromise. I

hope Mr. Dougherty recognizes that and that you may not get the whole loaf, but you might get half a loaf or three-quarters of a loaf by not pressing the more broad sides of the request for documentation.

MR. DOUGHERTY: Absolutely. And we've already tried to prioritize it and indicate in order of priority what our priorities are.

THE COURT: Well, I will entertain any document or any pleading that you file in that regard, Mr. Dougherty. And we'll also be pleased to have your guidance on the question of jurisdiction if you can so provide it. I won't give you a deadline. Obviously, the deadline is your own. But I think sooner rather than later, and I will act on it as soon as you get me the papers. Of course, if the SEC wishes to respond or file a joint pleading, that's all well and good.

MR. HUNTINGTON: Your Honor, I think for -- in terms of comity with another federal agency, we would probably need to stay on the sidelines. But we would certainly not object to anything reasonable that Mr. Dougherty tries to do.

THE COURT: If you want to respond in any way to what he does, do it quickly because, otherwise, I'll assume that you have no objection.

MR. HUNTINGTON: That's fine, your Honor. We can do that. We wanted to alert you months in advance of the fact discovery cut-off that this was coming. Hopefully --

THE COURT: That's an amended date already.

MR. HUNTINGTON: It was in light of the delays that they experienced earlier. We're on the same page that that will need to be extended somewhat further. But, I guess, how much further depends on whether they can get what they want from the FDA sooner rather than later.

THE COURT: We are reasonable in terms of allowing scheduling orders to be amended. It's just that we want to be in on it. If you all can agree to a scheduling amendment, it will, in all likelihood, be adopted the way you agree to it. This is a matter that I think is time-sensitive, and we ought to proceed diligently to try to resolve it.

MR. DOUGHERTY: We'll get our papers on this issue to your Honor within a week.

THE COURT: Thank you.

MR. DOUGHERTY: A week from today.

THE COURT: Anything else need to come to my attention?

MR. HUNTINGTON: Don't think so, your Honor.

(Whereupon, at 3:29 p.m. the hearing concluded.)

C E R T I F I C A T E

I, Cheryl Dahlstrom, RMR, and Official Reporter of the United States District Court, do hereby certify that the foregoing transcript, from Page 1 to Page 9, constitutes, to the best of my skill and ability, a true and accurate transcription of my stenotype notes taken in the matter of Civil Action No. 05-11805-NMG, Securities and Exchange Commission vs. Richard B. Selden.

_____

Cheryl Dahlstrom, RMR

Official Court Reporter

TAB E

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

RICHARD F. SELDEN,
Plaintiff,

V.

UNITED STATES FOOD AND DRUG ADMINISTRATION,
Defendant.

Civil Action No. 06-11807-NMG

November 3, 2006, 11:15 a.m.

TRANSCRIPT OF HEARING

BEFORE HONORABLE NATHANIEL M. GORTON

UNITED STATES DISTRICT COURT

JOHN J. MOAKLEY U.S. COURTHOUSE

ONE COURTHOUSE WAY

BOSTON, MA 02210

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P R O C E E D I N G S

(The following proceedings were held in open court before the Honorable Nathaniel M. Gorton, United States District Judge, United States District Court, District of Massachusetts, at the John J. Moakley United States Courthouse, 1 Courthouse Way, Boston, Massachusetts, on November 3, 2006.)

THE CLERK: This is civil action 06-11807, Richard Selden v. The U.S. Food and Drug Administration.

Counsel please identify themselves for the record.

MR. DOUGHERTY: Your Honor, for the plaintiff, Richard Selden, Thomas Dougherty, Justin Daniels.

THE COURT: Good morning Thomas Dougherty and Justin Daniels.

MR. QUINLIVAN: Good morning, your Honor. Mark Quinlivan for the defendants. With me is Jennifer Zachary from the Office of Chief Counsel of the FDA.

THE COURT: Good morning to you Mr. Quinlivan and Ms. Zachary.

MR. HUNTINGTON: Good morning, your Honor. Frank Huntington, David Butler for the Securities and Exchange Commission, and I guess we are technically intervenors today.

THE COURT: Yes. Good morning to you Mr. Huntington and Mr. Butler.

We are here this morning on this new matter of Selden v. U.S. Food and Drug Administration, which emanates

from an action before this session that we dealt with a little earlier involving the Securities and Exchange Commission against Mr. Selden and a subpoena -- or rather several subpoenas that were entered in that case to produce documents to the United States Food and Drug Administration.

And that matter proceeded in the United States District Court for the District of Columbia, which ultimately allowed the subpoenas to go forward and did not quash them. The Food and Drug Administration responded that it would take them something like 22 months to respond in toto, but, as I understand it, nevertheless, did start making production of documents.

I guess the first order of business before we get into the question of jurisdiction, which of course is crucial, is to find out what the status of the production of the documents is.

Maybe, Mr. Daniels, you can let me know what's going on in that regard, and then I'll hear from the Food and Drug Administration.

MR. DANIELS: Of course, your Honor. The production is continuing slowly, and the parties are still trying to negotiate and narrow the requests further in the hope that there will be resolution, but that there are --

THE COURT: And this is in connection with the matter that was submitted to this Court as a result of the

order of the United States District Court in the District of Columbia. And I have tried to peruse the Exhibit A that outlines all of the categories of documents that were to be produced, and it seems to me that the major stumbling block was the deliberative process privilege that was or is being claimed by the Food and Drug Administration and that apparently is the cause for the delay. Has that been dealt with in any significant way?

MR. DANIELS: I don't want to speak for the FDA, but my understanding of their position is that issue -- we disagree with it -- but that issue was not ripe because they actually haven't asserted it over any particular documents. And we would argue that that issue is certainly ripe because they've stated --

THE COURT: Is certainly what?

MR. DANIELS: Certainly ripe for judicial consideration because they've stated that they're not going to -- that they are not going to waive that privilege, as they've done in another very similar case, and that we understand that that is one of their reasons why they anticipate there being a 22-month production period. That and the question of confidentiality and trade secrets, those are the two, is what I think they anticipate being --

THE COURT: Maybe I should hear from Mr. Quinlivan or Ms. Zachary in that regard.

MR. QUINLIVAN: Thank you, your Honor. May it please the Court. With regard to production, as we set forth, the FDA has already produced 600 pages and anticipates the production of 8,400 more pages by December 31st of this year.

With regard to the remaining -- actually, I would say that the most significant stumbling block is a particular request regarding the -- what are investigatory new drug applications and the biological letter applications regarding a particular drug that might involve up to 125,000 pages of documents.

As we've set forth, if that request can be narrowed, that could knock off potentially somewhere between 5 and 19 months of that 22-month schedule.

The other aspect, which is most difficult about this, is that they have asked for every -- what -- it's -- the acronym is CLA, but it's every one going back to 1987, and there are approximately 9,229 in number. And the FDA does not have an automatic system to review those, and so what has to be done is to go through --

THE COURT: 9,000 documents or 9,000 boxes, or 9,000 what?

MR. QUINLIVAN: Well, there are 9,229 of these -- I think it's -- the CLAs, which have to be found within -- in other words, it's not simply a matter of opening a file and here are the 9,229. It would be as if somebody asked for every

document in this Court's session in which the government asserted the discretionary function exemption under the FTCA. One couldn't go either online or on Pacer and find that. One would have to literally go through every case to find where the United States was a defendant, and then in an FTCA case, where the deliberative process privilege exemption was asserted.

So because we're going back to 1987. Some of this is going to be literally page-by-page review to find these CLAs. So that also --

THE COURT: What does CLA stand for?

(Discussion off the record.)

MR. QUINLIVAN: I'm sorry, it's CRL, and it's what is known as the Complete Response Letter.

THE COURT: Complete Response Letter. Okay.

MR. QUINLIVAN: Now, I would point out -- and this is in the declaration of Ms. Sager -- that going back to the major stumbling block, I would say, which is the IND and BLA requests regarding the drug Fabrazyme -- and this is in paragraph 36 --

THE COURT: I'm not sure if I have that in front of me right now, but --

MR. QUINLIVAN: If your Honor --

THE COURT: Why don't you just --

MR. QUINLIVAN: I'd be happy to quote from it. It says, "Narrowing the subpoenas to exclude documents in the

Fabrazyme BLA and IND would save between 5 and 19 months of production time. The remaining requests for CDER documents and subpoenas are not anticipated to require a significant amount of resources."

Because of the deliberative process, because the FDA is in the process of collating and reviewing these materials, a determination has not been made at this time as to the trade secret redactions that need to be made, or where and when to assert the deliberative process privilege. So that, ultimately, may result in a stumbling block, but that is --

THE COURT: With that in mind, why not agree to some sort of protective order that limits the disclosure of any of this information to only those involved in this lawsuit? It's not, as I understand it, the intent of anybody to publicize any of this material to the general public. Its only relevance is to the SEC's claim against the plaintiff in this proceeding. So why can't the Food and Drug Administration agree to some sort of a protective order to avoid the necessity of having to make this search more onerous than it would otherwise be?

MR. QUINLIVAN: Well, your Honor, I think that if this were a Privacy Act action that that would be something -- because the Privacy Act has a particular statutory provision that allows a court to enter protective orders, and therefore, the material can be released. And I'm sure your Honor has

entered Privacy Act protective orders in litigation.

But the -- my understanding that the statutes and the regulations at issue here do not allow for that, or provide for that, and I'm not sure, for example, that even if the documents were produced pursuant to such a protective order, say regarding to the deliberative process privilege, that may very well constitute a waiver with respect to other -- I'm not sure that the fact that this Court -- that we agree to a protective order would necessarily immunize the documents from a waiver claim in other litigation.

THE COURT: Why is that? If it were in response to an order of a court to produce documents in connection with a specific litigation, you're contending that it would somehow constitute a waiver?

MR. QUINLIVAN: Well, I have not researched that question, your Honor, but I would say that this is, again, different from --

THE COURT: There's no precedent that I'm aware of that that has occurred in any other field, but, you know, I'm always willing to be educated. But I can't believe it would happen.

MR. QUINLIVAN: I'd be happy to take a look at that. But I think with respect to the trade secret, which is the more troubling, and I think --

(Discussion off the record.)

MR. QUINLIVAN: Pursuant to the statute -- and again, I'm just opposing this with the Privacy Act -- which has a provision that allows a protective order to be made whereby Privacy Act protected information can be revealed in court. The FDA statute at issue here prohibits the release of trade secret information to third parties, and it's set forth -- it's 18 USC section 1905, 21 USC 331(j).

There is no corresponding provision in those statutes that allows for the kind of protective order that can be entered in a Privacy Act matter.

MR. DANIELS: Your Honor, may I --

THE COURT: Okay. Yes, I'll hear you, Mr. Daniels.

MR. DANIELS: Thank you, your Honor. This is where the rubber hits the road. This is the issue that will cause this 5- to 19-month delay, so it obviously is critical to us.

THE COURT: Wait a minute. The delay that we were dealing with before was 22 months; and what Mr. Quinlivan has just said, if you could agree, you could save 5 to 19 months, right?

MR. DANIELS: Exactly. They're saying if we can agree to fully -- to not pursue this discovery at all, the discovery that we've already agreed to with the FDA, if we now go back on that and agree not to pursue that, then that would save the time.

But the reason that there is that delay is because

of their -- what they feel they're required to do, which is to redact all these documents. And I would point out to the Court that I did look at this question of protective orders being entered, and the fact --

THE COURT: With respect to trade secret information?

MR. DANIELS: With respect to trade secret information, your Honor. In fact, the law does provide for federal agencies to produce the documents under court order. And, for example, the statute that Mr. Quinlivan just cited, 18 USC 1905, provides that documents shall not be, you know, produced to the extent -- to any extent not authorized by law. And there are cases where the courts have held specifically that a discovery protective order is -- does include an authorization by law to produce it. And I'll just give you one example, your Honor, if that's okay: United States v. W.R. Grace, decided in August of this year, 2006, WestLaw 2942707. And the court specifically addressed the question of the Trade Secrets Act and stated that "The production of the documents in question is compelled by this court's discovery order, which the disclosure of the documents is authorized by law, therefore, the government must produce all documents identified it is withholding subject to the protective order."

I'll also mention that the FDA's own regulations provide for the disclosure of otherwise non-public information

in connection with court proceedings. And I will cite to the Court 21 CFR 20.86, which is titled Disclosure in Administrative or Court Proceedings. And it states, "The data and information otherwise exempt from public disclosure may be revealed under certain circumstances or court proceedings where data or information are relevant."

So with all due respect to Mr. Quinlivan, I think the law does provide for an exception in a case like this where the Court enters a protective order. And that is certainly under law providing for limited disclosure. And I think that given -- with a protective order, I think the question of deliberative process privilege and trade secret goes away; and the main cause of what appears to be what they're saying is the cause of what a projected 22-month delay is would go away.

Thank you.

THE COURT: All right. Mr. Quinlivan, do you want to respond to that?

MR. QUINLIVAN: Just briefly, your Honor.

With respect to the trade secret, because I think that is the more troubling question, I would like to emphasize, again, that the agency has not even decided whether it will assert the deliberative process privilege until its had the opportunity to review the documents.

But the fact is that not only does the statute prohibit the release of this information, but FDA's own

regulations, and I cite 21 CFR section 20.48, requires FDA to give notice to a person who will be affected by a proposed disclosure of data or information contained in Food and Drug records and permit them to institute suit in a U.S. District Court to enjoin the release of records.

So even if -- and we don't think a protective order of this sort is allowed by the law, but even if one was entered, you would literally have -- the FDA would be required to give notice to every company that is affected by this, and they would have the opportunity to file suit in this court to challenge the release of that information.

THE COURT: Well, okay. We've talked about the merits or demerits of the order of production before we've talked about the jurisdictional issue, which is whether or not this Court has jurisdiction to take over this matter.

As I understand it, the United States District Court in the District of Columbia, Judge Urbina, has under advisement a motion by the plaintiffs here, the defendants in the SEC case, to what, expedite the determination of what can and cannot be produced; is that right?

MR. DANIELS: Your Honor, there is no outstanding motion before the court in the District of Columbia. What -- when the court granted Dr. Selden's motion to compel, it asked the parties to submit a joint status report. And in that joint status report -- well, leading up to that joint status report,

I should say, the FDA counsel and myself spent many, many hours negotiating the scope of production, and that scope was agreed to but for one exception. We agreed to the scope of the production, and provided that information to the court and to this Court on August 25th. In addition to that, we provided what we considered to be open issues regarding the FDA's compliance with that order.

We would submit, your Honor, that that does not take away from the finality or the fact that that order is not final and can't be followed. The FDA itself is already agreeing to the substance of the production. The only other open issues --

THE COURT: Where does the ball lie now with respect to the District Court in the District of Columbia?

MR. DANIELS: Where does jurisdiction lie now?

THE COURT: Yes. As I understand it, your client requested a conference with the court and an order to enforce compliance with the subpoenas on a more deliberative timetable than the 22 months that was agreed to. What's the status of that?

MR. DANIELS: We had asked for a conference, your Honor. The FDA, I should say, opposed that request. We had offered to make a joint request for a conference, and the FDA said no. So we alone requested the conference before the court to discuss all of the open issues that we had listed, and there

is no -- we provided the court with these pleadings. We have not heard from the court with regard to that request.

THE COURT: So it was a motion for a hearing or a request --

MR. DANIELS: It was an informal -- not an informal -- it was not a motion. It was a line in the joint status report that says we respectively request a conference.

THE COURT: And you haven't followed up on that since August or September of this year?

MR. DANIELS: No. We were waiting on the court on that, and that's where that stood.

THE COURT: So is it your position that the District of Columbia court has anything more to do in this case or not?

MR. DANIELS: It's our position that the District of Columbia court does have authority to resolve those disputes, as this Court does have authority for different reasons. But that we are not expecting, although the court could call for a status conference. And if the court does, we would ask the court to respectively stay or hold the case in abeyance pending the outcome of the proceedings here. We aren't saying that our motions and papers that are filed in the District of Massachusetts somehow divests that court of authority over its own order.

THE COURT: All right. Mr. Quinlivan, on the other

side of the coin, why is it that you allege that this Court has no jurisdiction in this matter?

MR. QUINLIVAN: We do so, your Honor, based on the plain text of Rule 45 of the Federal Rules of Civil Procedure, whether it be with regard to the question of whether the issuance of a subpoena subjects a party to undue burden, whether under Rule 45(c)(1); whether it be whether a subpoena should be modified, quashed or enforced under 45(c)(3)(A); whether it be that a party should be held in contempt for failing to comply with a subpoena under Rule 45(e). All of those either talk about that the issuing court or the court on whose behalf the subpoenas were issued has the power, and the sole power to act. And that is why every court, including the DC Circuit, has held that the text of Rule 45 makes clear that only the issuing court has the power to enforce --

THE COURT: Couldn't the plaintiff have sought to have this Court issue the original subpoena? Doesn't this Court have jurisdiction over the Food and Drug Administration?

MR. QUINLIVAN: Well, the Food and Drug Administration is located in -- actually, in Maryland. And that was the plaintiff's decision, to issue --

THE COURT: They do business in Massachusetts and have an office here, do they not?

MR. QUINLIVAN: We do -- they do have an office here, yes.

THE COURT: So this Court would have been an appropriate court to have issued the subpoenas in the first place.

MR. QUINLIVAN: I don't think so, your Honor, because the documents in question are in Washington, D.C.

THE COURT: But the party seeking them is in Massachusetts, and it seems to me --

MR. QUINLIVAN: It's not a question -- with respect to Rule 45, it's not a question of where the party who is seeking them is located, it's based on the non-party where those documents are located, and that is -- quite frankly, you know, if the plaintiff had thought that a subpoena could issue from the District of Massachusetts, they could have attempted to issue the subpoenas here and we could have litigated that question. But they didn't. The fact of the matter is they were issued out of the District of Columbia, and with --

THE COURT: Isn't it your position that the District of Columbia court could not, if requested by the plaintiff, transfer the matter to Massachusetts?

MR. QUINLIVAN: It is our position, and I would note, and we pointed this --

THE COURT: Why couldn't they do that?

MR. QUINLIVAN: Well, because the D.C. Circuit in the In Re Sealed Case decided that the text of Rule 45 prohibits the transfer of such a motion.

There is, actually, a disagreement among the courts on that question. I point out -- in our memorandum in support of our motion to dismiss we pointed that out on page 12, footnote 5. We pointed out there actually are some courts, including the 8th Circuit and the District of Maryland, that have suggested that perhaps such a motion could be transferred.

The DC circuit in In Re Sealed Case rejected that argument and held it had no textual support. And in as much as Judge Urbina is bound by the decision at the D.C. Circuit, the U.S. District Court for the District of Columbia could not transfer that case to this Court.

THE COURT: Well, then why did Judge Urbina order the Food and Drug Administration to not only give it a joint status report, but to give this Court a joint status report back in its order of August 16th?

MR. QUINLIVAN: Well, I can't speak for Judge Urbina. I assume that as a matter of commodity he certainly -- given that the underlying action is in front of this Court, he wanted this Court to be aware of the proceedings in the District Court. But I don't think that that action in any way suggests that there is concurrent jurisdiction to act on a Rule 45 subpoena.

And I would point out, again, that in their response papers the plaintiffs have failed to cite a single case in which Rule 45 has been interpreted differently.

The only case they cite is an unpublished decision from the District of Kansas that merely states that where -- even where a subpoena is issued out of a different district court, the court where the action is pending, nonetheless, can enforce its own orders. In that case there was a discovery cutoff date that had already passed. And the court simply said I can enforce my own discovery cutoff date. It didn't act on the motion to quash the subpoenas issued by a different sister court.

THE COURT: It seems to me -- and just as a practical matter -- that this is the tail wagging the dog. The case at issue is pending in this Court. The subpoena that we are fighting about bears upon the issues that are relevant to an action before this Court, not the District Court of the District of Columbia. And to say that this Court has no standing or jurisdiction to do anything to protect the integrity of its docket and to move its cases along doesn't strike me as logical.

MR. QUINLIVAN: Your Honor, with respect, that's the judgment that Congress made when it enacted and put in force the text of Rule 45. And I would point out that the D.C. Circuit made that very point in the In Re Sealed Case. They made the point as a logical matter it may seem more -- it made more sense to have the court where the action is pending perhaps render a decision on the scope of discovery or the

timing of a response to a subpoena. But the court said Congress -- the balance that was struck by Congress was that rule -- to protect non-parties, Congress was going to limit jurisdiction to the issuing court.

So I'm not disagreeing with your Honor that it may make more practical sense, but as a legal matter -- and every court that has considered this question has come to that conclusion -- Rule 45 does not permit anything -- any court other than the issuing court to modify, quash, or, as here, enforce an order or a subpoena issued out of a different District Court. And the plaintiffs are trying -- the plaintiffs are trying to run away from the language of their own -- this complaint, where what they say is what we seek is meaningful compliance with the order issued by the District Court.

Putting aside the fact that there are several questions, significant questions that remain pending in front of Judge Urbina, most particularly Judge Urbina expressly said that he was not deciding whether the subpoenas were unduly burdensome. He put it in one of the subheadings of his opinion.

So the question about burdensome is still pending in front of Judge Urbina. And if the plaintiff wants to enforce that or if it thinks that the FDA is acting dilatory, then they had every opportunity to file an action in front of

Judge Urbina, the very same motion that they filed in this Court, seeking the relief.

Instead they came to this Court -- and I think when your Honor -- when your Honor had the SEC and plaintiff here in front of him in the September hearing, I think your Honor quite presciently noted that there's a serious question about jurisdiction here. You might be inclined to do something but you had to look at the jurisdictional question. And that's a question that the plaintiff has not answered here.

THE COURT: Mr. Daniels -- Mr. Dougherty.

MR. DOUGHERTY: Let me just address one aspect of this. There's no question, I think, and the government doesn't contend otherwise, that this Court has jurisdiction and control over its own docket. The remedies that this Court could apply with respect to that include some pretty strict remedies, including preclusion, and that I don't think is controverted.

So I believe that the Court has both jurisdiction over the docket and the matter and the FDA and remedies. They happen to be more extreme than the types of remedies available to a court in looking at and working through the burden and other relevance questions that may or may not be applicable to a subpoena. Relevance is usually not applicable to a subpoena or protective order.

THE COURT: Let me ask you the same question I asked Mr. Quinlivan. Do you believe that your client had the

option to seek a subpoena against the Food and Drug Administration in this court originally?

MR. DOUGHERTY: No, no. I think we agree with them on that. The way I have read it all my life is that the non-party and the location of the non-party and its documents in this case is the governing element. And then following that, your Honor asked about transfer. I am not sure -- that may -- I believe the DC Circuit has spoken on that with respect to its circuit.

So we thought we were compelled to go where we went. And then at the point that we thought we had a successful resolution from Judge Urbina, but we are running out of time with respect to this Court's trial schedule. And Judge Urbina had said that we should inform this Court, as we would have anyway, of his determination. We realized we need to proceed on two bases -- not get out ahead of Judge Urbina -- ask for that status conference, which they opposed.

We're happy to walk in there tomorrow and deal with that. Not inconsistently with here, I will say, but Judge Urbina does not have the trial schedule that this Court has for the Selden case that we have. And we're getting caught between, on the one hand, a very deliberative judge with a lot of things to do. You may have noticed if you look at the time between which the inputs and outputs came from Judge Urbina's court matters, they have a certain length to them. In

addition, there was a pending case in the D.C. Circuit that bore on the ultimate resolution here.

THE COURT: That's what I understood to be the main reason for his waiting.

MR. DOUGHERTY: Absolutely. And then we are -- so we are current, I think, with Judge Urbina. But this --

THE COURT: But you're not current with respect to the request that Mr. Daniels talked about, at least following up on the request made of him to make a determination as to whether 22 months was a timely compliance with the subpoena, right?

MR. DOUGHERTY: But timely in which sense, Judge? We are facing a trial schedule here, so that --

THE COURT: Well, presumably you've informed Judge Urbina --

MR. DOUGHERTY: Yes.

THE COURT: -- that you have obligations in another United States District Court case.

MR. DOUGHERTY: Yes, yes, yes. Absolutely. And so, therefore, we are happy to get direction, we're happy to proceed on either path, but without belaboring it, we absolutely think we are entitled to, and have pursued energetically the procuring of the relevant documents here. And we need to then proceed in a way that either -- either says to the FDA, look, you've even opposed a status conference,

you've opposed -- you've used every power you've had to oppose our applications. We can deal with that in that court, but if there's no other remedy available, then we would ask this Court for a preclusion order.

We're not going to be prejudiced having energetically pursued one path, and we'll keep pursuing it, but we're not going to be prejudiced on a trial schedule, respectfully, we would submit; and, if the remedy for that is preclusion, so be it.

THE COURT: Preclusion against the Securities and Exchange Commission.

MR. DOUGHERTY: Yes, who received without -- voluntarily and cooperatively from the FDA documents, including internal documents of the FDA in this matter that are the analog to what we are seeking, but without any -- voluntarily, cooperatively, without any of this, you know, effort that we've had to go through.

THE COURT: All right. Mr. Quinlivan, one more time, and I'll hear from the SEC.

MR. QUINLIVAN: Three points, briefly, your Honor. There's no pending motion in front of the District Court in DC. The plaintiff has not requested formally a hearing, a motion to enforce, or anything of that nature. A single line in a joint status report under the DC local rules is not sufficient. You actually have to move for a hearing.

Secondly, I've been reliably informed that the amount of documents that the FDA provided to the SEC is about that much (indicating). Nothing compared to the scope of the document production request that the plaintiff has asked for here, which can run up to 125,000 pages.

And, finally, if I could just -- on the question of efficiency, just so I can point your Court to the citation which is in the DC Circuit's decision in In Re Sealed Case, 141 F.3d at page 341. That's where the court said while the court in which the underlying litigation might in some circumstances be in a better position to adjudicate discovery disputes, quote, Congress and the rules has clearly been ready to sacrifice some efficiency in return for territorial protection for non-parties.

THE COURT: All right.

MR. QUINLIVAN: Thank you, your Honor.

THE COURT: Mr. Huntington, does the Securities and Exchange Commission have anything it wishes convey to the Court in this controversy?

MR. HUNTINGTON: Yes, your Honor, we do, not on the jurisdictional issue, but on the preclusion issue.

The issue in our case -- our case concerns what did the FDA say to the company and to Dr. Selden, and what did Dr. Selden and the company then say to investors? Our case does not involve internal deliberations of the FDA; it involves

what did the FDA say to the company, what did the company say to the investors?

Mr. Dougherty seems to have brought his set of our documents with him. I brought our set. This is what we got from the FDA (indicating). It's basically communications between the FDA and the company. I think Mr. Dougherty has his set right there. That was it. We took investigative testimony from precisely one FDA witness, Dr. Walton; they have that transcript. The FDA has offered to make Dr. Walton available for deposition.

Your Honor, I suspect we're being set up for a preclusion order that has no basis in the merits in our case.

Dr. Selden is asking for the entire file from the Genzyme application, which has nothing -- the fact that Genzyme had filed an application is mentioned in our complaint, but the merits of that application or the FDA's review of that application has nothing to do with the issues in our case, but will require them to redact tens of thousands of pages. No need for that.

They have asked for every one of those complete response letters for the last 15 or 20 years, none of which were mentioned in communications to the company, none of which Dr. Selden saw at the time, but somehow if they don't have those, they're going to be deprived of a fair defense.

I think we're being set up, your Honor. I don't

think it's fair.

THE COURT: Well -- okay. Final -- Mr. Dougherty, one last word.

MR. DOUGHERTY: Just because by way of example, there's no setup. These are materials voluntarily provided by the FDA to the SEC that relate to internal communications at the FDA, including e-mails to ten different people by the man at the top on this application --

THE COURT: So you don't have the same documents that Mr. Huntington has?

MR. DOUGHERTY: These were provided -- let me just finish. These were provided to the SEC on one theory, which was a mistake in theory that Mr. Selden and TKC somehow wanted to influence the timing of the advisory committee for an improper purpose.

What I'm getting at is that the statement what is at issue in this case is not internal communications is mistaken. We absolutely are looking for the equivalent -- this is only one issue that they pursued because they have one witness that they pursued in one respect and the documentation they found, we submit, will contradict their theory. But, more importantly, their pursuit was of --

THE COURT: First, let me understand -- wait a minute. Mr. Huntington says he has documents that were external documents from the FDA that seem to be about the same

volume as what you're holding; and you say those are internal documents, those are not the same documents.

MR. DOUGHERTY: No, these -- no. These documents are internal e-mails regarding the discussion within FDA of the advisory committee because they had the theory that TKT was trying to influence the timing of that. These were not externalized to TKT; these are internal. Similarly, with regard to these complete response letters on the defense of the case, we're going to show that inside the FDA the discussion and the assessment of TKT and where it stood at each point in time is much richer, much more complex and much more changing than the simple view of life that the SEC with its one witness wants to present. As a result of which, therefore, the discussions by TKT of where it was were in proportion in light of a much different situation than they are oversimplifying to make it look.

And we are entitled -- if this were a private case of private litigants and each side was asking for the internal documentation relevant to the issues in the case of the other, there would be no discussion; they would be provided. And here, that's what we are asking for, is how the FDA assessed TKT at each stage --

THE COURT: Except that, apparently, you're asking for hundreds of thousands of documents.

MR. DOUGHERTY: I think that overstates it. Let's

go into -- it breaks down into three parts. We have said to them with respect to the TKT information that TKT provided to the FDA, we don't need it back, we already have that. But in their complaint they acknowledge and they criticize TKT for misstating its situation in the race for orphan drug approval against another company, Genzyme. It's right in the complaint that TKT was misstating its position and its place in the race with Genzyme. So that is why we have asked for the equivalent documentation relating to FDA's consideration of TKT and Genzyme, because that's what was happening at the same time. And we are going to show that we didn't misstate the relationship in the race with Genzyme. So that's why there are documents --

THE COURT: Why can't the extent of that documentation be limited? Why does it have to extend to the entire Genzyme application?

MR. DOUGHERTY: We have negotiated with them -- and it's on the exhibit --

THE COURT: Them meaning whom?

MR. DOUGHERTY: The FDA. In fact, the Exhibit A to Judge Urbina and to this Court, the very first paragraph is the negotiated scope related to Fabrazyme, that's the Genzyme product. And the FDA's position on that was subject to the issue of redaction and privacy and trade secret. The redaction could take considerable period of time, but that, in and of

itself, these documents on Fabrazyme are not otherwise so burdensome as to not be producible in the negotiated resolution you see.

This is a situation in which TKT and Mr. Sullivan have produced over 50,000 pages of documents.

So we're happy to work with them. We already did all summer with regard to the scope on that. And during that time frame, the SEC was aware that we were working on that negotiation and never interceded on that negotiation and never took the position that they're now taking that somehow or another they should be off limits.

And the next -- the next and last that I'll say is with regard to the CRLs, the Complete Response Letters. We would be happy to limit that to the Complete Response Letters from January 1, 1998 through December of 2002, which is the time frame of the pendency of this TKT application, and limit it to CBER, C-B-E-R, which is the subset within -- subdivision within FDA. We'd do that right now. And that is not a large undertaking, but it is central to our case. Why? Because, again, we're going to show that the way in which this company reflected that Complete Response Letter was absolutely standard. We're going to show that. And we can show that both with respect to -- you know.

THE COURT: All right. Thank you, counsel.

What I'm going to do is this: I'm going to extend

the time periods for discovery that are either expired or about to expire 90 days. I'm going to instruct the plaintiff in this case, the defendant in the related case, that is Mr. Selden and its counsel, to pursue with all due diligence whatever remedy it believes, he believes, it has in the District Court for the District of Columbia with regard to the compliance by the Food and Drug Administration with the outstanding subpoenas, including, if he sees fit, any motion to that court to involve this Court in the process. That is, if there is an availability of transfer of jurisdiction over this matter -- the FDA claims there is none, I'm not so sure, but that is up to the plaintiff to follow up. But, in any event, to pursue as diligently as possible with the understanding that it has now a requirement that is put off by 90 days to complete the discovery in the SEC litigation.

If either the plaintiff or the Food and Drug Administration want to further advise this Court on whether or not this Court can do anything further with respect to the controversy involving the discoverable documents, then I will entertain such further legal advice. Otherwise, I will take the matter under advisement, both the FDA's motion to dismiss and Mr. Selden's motion for a preliminary injunction. I'm not going to act upon them now. I'm going to review all of these papers. But with respect to the SEC case, the matter is delayed 90 days, but no more. We will see what transpires.

The District Court of the District of Columbia should be advised of the matter present in this Court and understand what the status of the discovery order is here.

Yes, Mr. Huntington, before we adjourn.

MR. HUNTINGTON: Yes, your Honor. About a week ago, Dr. Sullivan filed a motion to preclude directed to the Commission. I guess my question is: Is your Honor going to put that to the side while we resolve these issues, or do you want our position --

THE COURT: That matter will be taken under advisement, and you do not need to answer at this time. We'll wait and see what happens in the preceding 90 days.

MR. HUNTINGTON: Thank you, your Honor.

THE CLERK: All rise.

(Court adjourned at 12:00 p.m.)

CERTIFICATION

I certify that the foregoing is a correct transcript of the record of proceedings in the above¡entitled matter to the best of my skill and ability.

_____ _____

Debra M. Joyce Date

Official Court Reporter